EXHIBIT 6 PART 1

EFILED 08/03/22 02:25 PM CASE NO. 22C1563 Richard R. Rooker, Clerk

IN THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL DISTRICT
DAVIDSON COUNTY, TENNESSEE

BABY DOE and BROTHER DOE; BABY ROE, BROTHER ROE, and SISTER ROE; and BABY SMITH, by and through their guardian *ad litem,*	)	
Plaintiffs,	)	
v.	)	
ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.; IMPAX LABORATORIES; AMNEAL PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS, LLC; TEVA PHARMACEUTICALS USA, INC.; ALLERGAN FINANCES, LLC; ACTAVIS, LLC; ACTAVIS PHARMA INC.; WATSON LABORATORIES; JOHNSON & JOHNSON, INC.; JANSSEN PHARMACEUTICALS, INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; MCKESSON CORPORATION; CVS PHARMACY, INC; CVS TN DISTRIBUTION, LLC; CVS INDIANA, LLC; TENNESSEE CVS PHARMACY, LLC; RITE AID HDQTRS. CORP.; RITE AID OF TENNESSEE, INC.; RITE AID OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.; WALGREEN CO.; WALMART INC.; WAL-MART STORES EAST, L.P.; TIMOTHY ABBOTT;	)	**Civil Action No.: _____** **JURY DEMAND**

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CINDY SCOTT;)
HEMAL MEHTA;)
HEATHER MARKS;)
JAMES MACCARONE; and)
DEL MAR MEDICAL, INC. d/b/a)
PARDUE'S PHARMACY,)
)
Defendants.)

COMPLAINT

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1. This is an action brought by six babies born dependent on opioids (collectively "the Baby Doe Plaintiffs")[1] against major drug producers, drug distributors, chain and independent pharmacies, and pill mill prescribers under the Tennessee Drug Dealer Liability Act ("DDLA"). This action seeks compensation for the harm inflicted on these children by Defendants' unscrupulous and immoral expansion of the illegal opioid market, harm which they experienced from their first moments of life as they suffered from opioid withdrawal and continue to experience to this day as they struggle with the residual behavioral issues and learning disabilities caused by their *in utero* exposure to opioids.

INTRODUCTION

2. The opioid epidemic poses an ongoing crisis in Tennessee. From 2012 to 2020 (the last year for which data has been reported), Tennessee set a new state record each year for the number of opioid overdose deaths, with 1,543 in 2019 and 2,388 in 2020.[2] According to IMS Health data, in 2015, there were also a staggering 7.8 million opioid painkiller prescriptions filled

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[1] Plaintiffs are simultaneously filing a Motion to Proceed by Pseudonym to request permission to use pseudonyms in this action to protect the Baby Doe Plaintiffs' and family members' identities.

[2] Tennessee Department of Health, Tennessee Drug Overdose Data Dashboard. Available at: https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html. (hereinafter "Tennessee Drug Overdose Data Dashboard").

in the state – or 1.18 prescriptions for every man, woman, and child, placing Tennessee at number 2 in the nation among all states for the number of opioid prescriptions per capita. This trend continued, as evidenced by the CDC report, which showed that Tennessee providers wrote 68.5 opioid prescriptions per 100 persons in 2020, the third highest prescribing rate in the country and more than the average U.S. rate of 43.3 prescriptions.[3]

3. Along with overdose deaths, the number of babies born with neonatal abstinence syndrome ("NAS") - a condition suffered by babies born to mothers addicted to opioids - has also increased dramatically in Tennessee. In 2020 alone, there were 824 NAS births in Tennessee.[4]

4. The Baby Doe Plaintiffs were born dependent on opioids. Like the tragedy that besets thousands of children born dependent on opioids every year, the first days of their lives were spent in excruciating pain, while doctors attempted to wean them from their opioid dependency. The Baby Doe Plaintiffs' birth mothers fell victim to an epidemic that has ravaged Tennessee, causing immense suffering to those born addicted to opioids. The Tennessee community into which the Baby Doe Plaintiffs were born is plagued by the opioid epidemic, resulting in high rates of addiction, record numbers of overdose deaths, alarming rates of babies born opioid-dependent, and an illegal opioids market that continues to thrive despite the best efforts of law enforcement to combat it.

5. The opioid epidemic did not appear overnight. It is the consequence of unconscionable greed perpetrated by the following groups of Defendants, who fueled the rampant

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[3] Center for Disease Control, *U.S. State Opioid Dispensing Rates, 2020* https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html.

[4] Tennessee Department of Health, *Neonatal Abstinence Syndrome (NAS),* https://www.tn.gov/health/nas.html (hereinafter "Tennessee NAS Dasboard").

addiction to opioid drugs through unbridled distribution in pursuit of profit that still ravages the general public welfare:

a. The **"Producer Defendants" or "Drug Producer Defendants":** ACTAVIS LLC, ACTAVIS PHARMA, INC., ALLERGAN FINANCES, LLC, and WATSON LABORATORIES, INC. (collectively "Allergan"); AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS, LLC, and IMPAX LABORATORIES, LLC (collectively "Amneal"); ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS, INC. (collectively "Endo"); JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON, INC. (collectively "J&J); PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC. ("Par"), and TEVA PHARMACEUTICAL USA, INC. ("Teva");

b. The **"Drug Distributor Defendants" or "the Distributor Defendants"**: AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen"), CARDINAL HEALTH, INC. ("Cardinal Health"), and MCKESSON CORPORATION ("McKesson") ;

c. The **"Pharmacy Chain Defendants"**: CVS PHARMACY, INC., CVS TN DISTRIBUTION LLC, CVS INDIANA, LLC, TENNESSEE CVS PHARMACY, LLC (collectively "CVS"), RITE AID HDQTRS CORPORATION, RITE AID OF TENNESSEE, INC., RITE AID OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER (collectively "Rite Aid"),

WALGREEN CO. ("Walgreens") and WALMART INC. and WAL-MART STORES EAST, L.P. (collectively "Walmart") .

d. The **"Pill Mill Defendants"**: TIMOTHY ABBOTT, CINDY SCOTT, HEMAL MEHTA, HEATHER MARKS, JAMES MACCARONE, DEL MAR MEDICAL, INC. d/b/a PARDUE'S PHARMACY

6. Despite knowing about widespread diversion and illegal distribution by such actors as the Pill Mill Defendants, the opioid producers, distributors, and retailers continued to flood Tennessee with their highly addictive prescription drugs, which both perpetuated their multi-billion dollar drug empire and propelled opioid abuse to unprecedented levels. As described herein, the Producer Defendants, the Distributor Defendants, the Pharmacy Chain Defendants, and the Pill Mill Defendants committed various acts that were intended to—and did—facilitate illegal diversion of their drugs.

7. The Baby Doe Plaintiffs are victims of Defendants' avarice. They were each born dependent on opioids and forced to endure painful starts to their lives: crying excessively, arching their backs, refusing to feed, and shaking. After more than a decade of unbridled distribution of prescription opioids by Defendants, their birth mothers' community was awash in painkillers, fueling a dramatic increase in those exposed to and addicted to opioids.

8. Indeed, Defendants spent years convincing suspicious doctors that prescription opioids' addictive properties had been overblown, aggressively marketing opioids, and/or filling suspicious orders and suspicious prescriptions even when these Defendants knew that millions of Americans and hundreds of thousands of Tennesseans were abusing and misusing prescription opioids. Defendants knew that entire regions of the country were being devastated by addiction to prescription drugs that they distributed. They also recognized that prescribers were writing – and

pharmacies filling – volumes of opioids that necessarily were both creating and supplying large volumes of drug addicts and pill seekers. Nevertheless, the Drug Producer Defendants, Drug Distributor Defendants, Pharmacy Chain Defendants, and Pill Mill Defendants persisted with distributing mind-boggling volumes of opioids into these same abuse-riddled communities, peddling the same misinformation to overcome prescribers' legitimate objections, urging suspect prescribers and pharmacies that supplied the illegal market to flood the market with even more opioids, and otherwise taking various measures to ensure that the flow of prescription opioids to feed drug addicts and pill seekers proceeded without impediment.

9. Under Tennessee law, prescription opioids are controlled substances because they inherently have a "high potential for abuse" and that "may lead to severe psychic or physical dependence."[5] For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must ensure that the drugs are only being distributed to serve legitimate medical purposes.[6] If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee. Indeed, entities holding a Tennessee license can be criminally prosecuted for violating their responsibilities in the distribution chain.[7] The Producer Defendants, Distributor Defendants, and Pharmacy Chain defendants did not lawfully distribute prescription opioids into or within Tennessee. Instead, using their licenses as a cover, they unlawfully distributed drugs without maintaining necessary controls (rendering the distribution unlawful), knowingly distributed those drugs into channels that they knew were resulting in diversion, knowingly

[5] Tenn. Code Ann. § 39-17-407.
[6] *See, e.g.*, Tenn. Code Ann. § 53-11-302, -303, -312(c), 401(a), *and* Rules of Tenn. Bd. Of Pharmacy, Ch. 1140-02.01; *see also* Tenn. Code Ann.§ 53-10-312.
[7] *See* Tenn. Code Ann. § 53-11-401.

encouraged high-volume pill mill prescribers to prescribe opioids without a legitimate medical purpose to feed drug abusers, pill seekers, and drug dealers, knowingly supplied pharmacies serving pill mills, and knowingly dispensed prescriptions that were not made for a legitimate medical purpose.

10. The Producer Defendants also committed various other acts intended to facilitate diversion and illegal drug sales, from which they knowingly sought to profit. These acts include, inter alia: waging a public campaign of misinformation concerning opioids (including through "key opinion leaders" and front groups); encouraging prescribers to engage in prescription practices that the Producer Defendants knew and expected would drive up addiction rates; repeatedly calling on and targeting the highest volume prescribers to prescribe more opioids while knowing that those prescribers were or were likely operating pill mills; convincing naïve doctors willing to write prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale; devising marketing strategies to overcome prescribers' legitimate objections to prescribing opioids for long-term use and in higher doses; convincing prescribers whom defendants knew were likely engaging in unlawful conduct and feeding the illegal drug market to prescribe even more opioids; incentivizing sales representatives to do business both with pill mills and with pharmacies supplying pill mills through volume-based compensation (and financially rewarding those sales associates for doing so); adding high-volume prescribers and pharmacies as customers without any due diligence, knowing that there was a strong likelihood that these high-volume businesses were running or supplying pill mills; filling suspicious orders despite knowing or reasonably suspecting that the orders reflected diversion; filling suspicious orders without any investigation; filling suspicious orders even where they met the Producer Defendants' own criteria for orders reflecting potential diversion; filling orders that

they had subjectively identified as suspicious before undertaking or completing an investigation; continuing to do business with prescribers and pharmacies that had a history of suspicious prescribing or ordering practices; implementing sham suspicious order monitoring programs that were structured to fail and to allow diversion to proceed unimpeded; continuing to target pill mill prescribers to prescribe more opioids and to target associated pharmacies that served them, even after being told by law enforcement that they were likely feeding the illegal drug market; supplying outlandish volumes of prescription opioids to Tennessee communities far exceeding any conceivable medical need; and over-supplying Tennessee with opioids while recognizing that doing so would create addicts and expand the illegal drug market. Defendants' actions included encouraging higher volumes of prescriptions, supplying, and otherwise doing business with entities in Tennessee patently engaging in diversion, such as Timothy Abbott, Cindy Scott, and the other Pill Mill Defendants.

11. The Distributor Defendants and the Pharmacy Chain Defendants similarly committed acts intended to facilitate the diversion of drugs into the illegal drug market in Tennessee. The Distributor Defendants and the Pharmacy Chain Defendants are or were major distributors of controlled substances. Like the Producer Defendants, the Distributor Defendants and the Pharmacy Chain Defendants were aware of (and helped cause) a growing epidemic from abuse, addiction, and diversion of the prescription opioids they supplied nationwide and in Tennessee. They were aware of the quantities and frequency with which those drugs were distributed in Tennessee and the Baby Doe Plaintiffs' community, and they knew with reasonable certainty which prescribers were operating pill mills (or otherwise over-prescribing) and which pharmacies were filling those prescriptions. Nevertheless, they chose to do business with pharmacies and dispensing physicians whom they knew or reasonably believed were feeding the

illegal drug market. Furthermore, the Distributor Defendants and the Pharmacy Chain Defendants recognized that they had a responsibility not to fill suspicious orders, because filling those orders would foster diversion into the illegal drug market. They knew what types of orders were indicative of diversion, such as frequent and large orders by pharmacies in rural communities with low population, orders by pharmacies that they recognized were serving pill mill operators, sharp increases in order volume without justification, orders for tablets exceeding the number of people in a community, and orders by pharmacies that they knew were filling prescriptions from "patients" who traveled hundreds of miles to fill the prescriptions. Despite recognizing orders that reflected diversion, they processed and filled them anyway. Moreover, they intentionally ensured that they had no meaningful controls against diversion and intentionally structured their supposed suspicious order monitoring systems to fail.

12. Moreover, everyone in the distribution chain collaborated to get around whatever sham suspicious order monitoring systems that the drug producers may have put in place. They offered sham justifications for suspicious orders that everyone in the chain accepted without accepted without question, no matter how ludicrous – thereby giving the Producer Defendants, Distributor Defendants, and the Pharmacy Chain Defendants a convenient pretense to make, fill, and ship orders that they knew would supply the illegal drug market. Through this symbiotic relationship, they persisted in filling suspicious orders for large volumes of products, calling on suspicious subscribers and pharmacies, filling suspicious prescriptions, and/or otherwise shipping drugs to Tennessee communities ravaged by the opioid epidemic at levels far exceeding any conceivable need. They knew that their actions would cause (and in fact did cause) increased abuse, addiction, and overdose rates in Tennessee. They also knew that their actions facilitated illegal drug transactions in Tennessee.

13. The Pill Mill Defendants also facilitated the illegal opioid market in Tennessee. They knowingly supplied suspicious quantities of opioids to patients that exhibited blatant red flags of diversion. They knowingly failed to implement effective controls and procedures to guard against the diversion of opioids. Each Pill Mill Defendant knew that the amount of opioids they were prescribing/dispensing were not medically justified, and each became popular destinations for drug addicts and dealers to obtain opioids. Their actions fueled the illegal drug market in the Baby Doe Plaintiffs' community.

14. Defendants' actions caused—and continue to cause—the Baby Doe Plaintiffs, their birth mothers, and thousands of other Tennesseans to become addicted to opioids – an addiction that, as they well knew, was all but certain to occur. It is also beyond question that Defendants are aware that: opioids continue to be over-prescribed in Tennessee—including in the Baby Doe Plaintiffs' community—at levels far beyond what could be medically justified; that a legion of addicts are obtaining pills on the black market or through "pill mills" to satisfy their addiction; that a significant share of the opioids market in Tennessee consists of illegal drug transactions; that they are doing business with pill mills; and that they are knowingly reaping profits from drug sales in the illegal drug market.

15. Defendants' misconduct garnered significant profits. In 2010 alone, opioids generated $11 billion in revenue for drug companies.[8] Opioids are now among the most prescribed class of drugs and the United States' opioid painkiller market is worth an estimated $10 billion annually.[9] According to Fortune magazine, the Distributor Defendants are each among the top 15

[8] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune.com, Nov. 9, 2011. Available at: http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/.
[9] Ariana Eunjung Cha, *The drug industry's answer to opioid addiction: More pills*, The Washington Post, Oct. 16, 2016. Available at: https://www.washingtonpost.com/national/the-

companies in the 2022 Fortune 500: McKesson, No. 9, with $238 billion in total revenue; AmerisourceBergen, No. 10, with $213 billion in total revenue; and Cardinal Health, No. 15, with $162 billion in total revenue.[10]

16. The Baby Doe Plaintiffs now sue to recover damages for which Defendants are liable under the DDLA.

JURISIDICTION AND VENUE

17. Jurisdiction is proper pursuant to Tenn. Code Ann. § 16-10-101, *et seq.*, and Tennessee's Drug Dealer Liability Act, Tenn. Code Ann. § 29-38-101, *et seq.* The Baby Doe Plaintiffs were all born in Davidson County, Tennessee. Their birth mothers used and made unlawful purchases of drugs in Davidson County.

18. Venue is proper pursuant to Tenn. Code Ann. § 20-4-101 because the Baby Doe Plaintiffs were born in Davidson County, reside in Davidson County, and their birth mothers purchased and consumed illegal opioids in Davidson County.

PARTIES

A. Plaintiffs

19. The Baby Doe Plaintiffs are six children between the ages of 2 and 8.

20. Plaintiffs BABY DOE and BROTHER DOE were born with NAS as a result of their exposure *in utero* to illegal drugs, including but not limited to Opana, Roxicodone, hydrocodone, hydromorphone, oxycodone, and other opioids. These drug exposures provide them with the right to sue for damages under the DDLA.

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drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.42e0328ca459.

[10] https://fortune.com/fortune500/2022/search/

21. Plaintiffs BABY ROE, BROTHER ROE, and SISTER ROE were born with NAS as a result of their exposure *in utero* to illegal drugs, including but not limited to Opana, Percocet, Roxicodone, Lortab, hydrocodone, oxycodone, fentanyl, and other opioids. These drug exposures provide them with the right to sue for damages under the DDLA

22. Plaintiff BABY SMITH was born with NAS as a result of his exposure *in utero* to illegal drugs, including but not limited to Percocet, Lortab, hydrocodone, oxycodone, and other opioids. These drug exposures provide him with the right to sue for damages under the DDLA.

23. The Producer Defendants produced opioids and otherwise contributed to the illegal drug market that caused the Baby Doe Plaintiffs harm. The Distributor Defendants and the Pharmacy Chain Defendants distributed opioids and otherwise contributed to the illegal drug market that caused the Baby Doe Plaintiffs harm. The Pill Mill Defendants prescribed and dispensed opioids and otherwise contributed to the illegal drug market that caused the Baby Doe Plaintiffs harm.

24. The Baby Doe Plaintiffs bring this action by and through their guardian *ad litem*. Legal guardians of children exposed to illegal drugs *in utero* are authorized to bring this action under the DDLA. Tenn. Code Ann. § 29-38-106(a)(1).

B. The Drug Producer Defendants

1. Allergan

25. Defendant ALLERGAN FINANCES, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.) is a Nevada limited liability company that exists for the purpose of holding shares of other companies that manufacture and distribute prescription pharmaceuticals. Its sole member is Allergan W.C. Holding Inc. f/k/a Actavis W.C. Holding Inc., a Delaware corporation with its principal place of business in Madison, New Jersey. It is a wholly owned, indirect

subsidiary of Allergan PLC. It may be served through its registered agent The Corporation Trust Company of Nevada, 701 S. Carson Street, Suite 200, Carson City, Nevada 89701.

26. Defendant WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California. It may be served through its registered agent Corporate Creations Network Inc., 8275 South Eastern Avenue, #200, Las Vegas, Nevada 89123.

27. Defendant ACTAVIS PHARMA, INC. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey. It may be served through its registered agent Corporation Service Company, 2908 Poston Avenue, Nashville, Tennessee 37203.

28. Defendant ACTAVIS LLC (f/k/a Actavis Inc.) is a Delaware limited liability company with its principal place of business in New Jersey. It may be served through its registered agent Corporation Service Company, 2908 Poston Avenue, Nashville, Tennessee 37203.

29. Until August 2016 when they were sold to Teva, Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis LLC were owned by Allergan plc.

30. During the time period described herein and until they were sold to Teva Pharmaceuticals Industries Ltd. in August 2016, Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis LLC were part of the same corporate family as Allergan Finance, LLC and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan Finance, LLC, Actavis Pharma, Inc., and Actavis LLC.

31. The above-identified Defendants and their subsidiaries and affiliates are referred to collectively as "Allergan." Further, "Allergan" only refers to Actavis Pharma, Inc. and Actavis LLC until August 2016.

2. Endo

32. Defendant ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

33. Defendant ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of ENDO HEALTH SOLUTIONS INC., and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS INC. are referred to collectively as "Endo."

34. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Tennessee. Endo also produces and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Tennessee, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Qualitest included multiple wholly owned subsidiaries of Endo. It operated as the generic arm of Endo at least until Endo and Par merged. Endo is liable for the manufacture and distribution of generic drugs through Qualitest, including (*inter alia*) shipping without diversion control.

35. ENDO HEALTH SOLUTIONS INC. can be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. ENDO PHARMACEUTICALS INC. can be served through its registered agent: CT Corporation System, 800 S. Gay Street, Suite 2021, Knoxville, Tennessee 37929.

3. J&J

36. Defendant JOHNSON & JOHNSON, INC. is a New Jersey corporation that is headquartered in New Jersey.

37. Defendant JANSSEN PHARMACEUTICALS, INC. (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.) is a Pennsylvania corporation headquartered in New Jersey. Janssen is a

wholly-owned subsidiary of Johnson & Johnson, which controls the sale and development of Janssen's drugs. Janssen's profits inure to Johnson & Johnson's benefit. Janssen and Johnson & Johnson are collectively referred to herein as "J&J."

38. JOHNSON & JOHNSON, INC. and JANSSEN PHARMACEUTICALS, INC. can both be served through their registered agent, CT Corporation Systems, 300 Montvue Road, Knoxville, Tennessee 37919.

4. Impax/Amneal

39. Defendant IMPAX LABORATORIES, LLC (f/k/a Impax Laboratories, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Impax is engaged in the business of developing, manufacturing, and marketing pharmaceuticals, including oxymorphone ER. Unless otherwise specified, "Impax" refers to Impax Laboratories, LLC and all corporate predecessors, subsidiaries, successors, and affiliates.

40. Defendant AMNEAL PHARMACEUTICALS, INC. is a Delaware business entity with its principal place of business in New Jersey. Amneal Pharmaceuticals, Inc. was created when Defendant AMNEAL PHARMACETUICALS, LLC merged with Impax on October 4, 2017. As a result of this merger, Amneal Pharmaceuticals LLC now wholly owns Impax and is the operating company for the combined business, which includes selling oxymorphone ER. Unless otherwise specified, "Amneal" refers to Amneal Pharmaceuticals, Inc. and all corporate predecessors, subsidiaries, successors, and affiliates, including Impax.

41. AMNEAL PHARMACEUTICALS, INC. and AMNEAL PHARMACETICALS, LLC may be served at its principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. IMPAX LABORATORIES, INC. may be served at its principal place of business at 100 Somerset Corporate Blvd #3000, Bridgewater New Jersey 08807.

5. Par

42. Defendant PAR PHARMACEUTICAL, INC. is a Delaware Corporation with its principal place of business in Chestnut Ridge, New York and is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant PAR PHARMACEUTICAL COMPANIES, INC. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") were acquired by Endo International plc in September 2015 and serve as operating companies of Endo International plc. Subsequent to their acquisition, Par was merged with Qualitest, and serves as Endo's generic pharmaceutical manufacturer.

43. At all times relevant to this complaint, Par produced and sold generic opioids including, but not limited to, oxycodone, hydrocodone, and oxymorphone.

44. PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PARMACEUTICAL HOLDINGS, INC. can be served through their registered agent: CT Corporation System, 28 Liberty St., New York, New York 10005.

6. Teva

45. TEVA PHARMACEUTICALS USA, INC. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. TEVA PHARMACEUTICALS USA, INC. is a wholly owned subsidiary of Teva Pharmaceuticals Industries, Ltd., an Israeli corporation. Cephalon, Inc. is also a wholly owned subsidiary of Teva Pharmaceuticals Industries, Ltd. In August 2016, Teva Industries, Ltd. bought Actavis Pharma, Inc. and Actavis LLC from Allergan Plc. Thus, since August 2016, Teva Industries, Ltd. has owned the generic business that was formerly owned by Allergan. Hereinafter, TEVA PHARMACEUTICALS USA, INC., Teva

Pharmaceuticals Industries, Ltd., Actavis Pharma, Inc., Actavis LLC, and Cephalon, Inc. are collectively referred to as "Teva."

46. Inclusive of companies and product lines it has acquired, Teva develops, markets, and sells prescription drugs, including opioids. In 2011, Teva purchased Cephalon, which was manufacturing a branded opioid called "Actiq" (a branded opioid containing fentanyl) and Fentora (an oral tablet form of fentanyl). Teva marketed and sold both Actiq and Fentora in Tennessee. In 2016, Teva purchased Actavis, which produces generic opioids. In Tennessee and nationally, Teva is engaged in the production, promotion, and distribution of generic opioids, including hydrocodone and oxycodone among other drugs.

47. Teva can be served through its registered agent: Corporate Creations Network, Inc., 3411 Silverside Road, Tatnall Building, Ste. 104, Wilmington, DE 19810.

B. The Drug Distributor Defendants

1. AmerisourceBergen

48. Defendant AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") is a Delaware corporation with its principal place of business located at 1300 Morris Drive in Chesterbrook, Pennsylvania 19087. AmerisourceBergen and its affiliates hold multiple wholesaler/distributor licenses in Tennessee.

49. AmerisourceBergen, through various subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes prescription opioids throughout the country, including in Baby Doe Plaintiffs' community for the Producer Defendants and others. AmerisourceBergen is the second largest pharmaceutical distributor in North America. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and

pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care." In 2018, AmerisourceBergen was the 11th largest company by revenue in the United States.

50. AmerisourceBergen distributes opioids that are produced by Producer Defendants throughout Tennessee, including opioids within the Baby Doe Plaintiffs' community and the associated illegal drug market. AmerisourceBergen established direct relationships with Tennessee pharmacies, including in the Baby Doe Plaintiffs' community.

51. At all times relevant, AmerisourceBergen and its affiliates have been licensed as wholesalers/distributors in Tennessee, and currently hold multiple Tennessee licenses.

52. AmerisourceBergen can be served through its registered agent, the C T Corporation System, 300 Montvue Rd, Knoxville, TN 37919.

2. Cardinal

53. Defendant CARDINAL HEALTH, INC. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

54. Cardinal distributes opioids that are manufactured by Producer Defendants throughout Tennessee, including opioids within the Baby Doe Plaintiffs' community and the associated illegal drug market. Cardinal Health established direct relationships with Tennessee pharmacies, including in the Baby Doe Plaintiffs' community.

55. At all times relevant, Cardinal and its affiliates have been licensed as wholesalers/distributors in Tennessee, and currently holds multiple Tennessee licenses.

56. Cardinal can be served through its registered agent, CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, OH 43219.

3. McKesson

57. Defendant MCKESSON CORPORATION ("McKesson") is a Delaware Corporation with its principal place of business located in San Francisco, California.

58. McKesson distributes opioids that are manufactured by Producer Defendants throughout Tennessee, including opioids within the Baby Doe Plaintiffs' community and the associated illegal drug market. McKesson established direct relationships with Tennessee pharmacies and dispensing physicians, including those in the Baby Doe Plaintiffs' community.

59. At all times relevant, McKesson and its affiliates have been licensed as wholesalers/distributors in Tennessee, and currently holds multiple Tennessee licenses.

60. McKesson can be served through its registered agent, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808. It can also be served through its registered agent in Tennessee, Corporation Service Company, 2908 Poston Ave, Nashville, TN 37203.

61. Collectively, McKesson, AmerisourceBergen, and Cardinal Health currently account for 95 percent of the drug shipments in the United States. These companies together collect about $400 billion in annual revenue.

D. The Pharmacy Chain Defendants

1. CVS

62. Defendant CVS PHARMACY, INC. is a Rhode Island corporation with its headquarters and principal place of business in Woonsocket, Rhode Island. Defendant CVS TN DISTRIBUTION LLC (f/k/a CVS TN Distribution, Inc.) is a Tennessee limited-liability corporation and subsidiary of CVS Pharmacy, Inc. with a principal office in Woonsocket, Rhode Island. Defendant CVS INDIANA, LLC is an Indiana corporation and a subsidiary of CVS Pharmacy, Inc. Defendant TENNESSEE CVS PHARMACY, LLC is a Tennessee limited-liability

corporation and a subsidiary of CVS Pharmacy, Inc. with its principal place of business in Woonsocket, Rhode Island. Collectively, these entities are referred to as "CVS."

63. CVS self-distributed opioids to its locations in Tennessee. At all times relevant, CVS has been licensed as a wholesaler/distributor in Tennessee.

64. The CVS entities can be served with process via its registered agent in Tennessee, CT Corporation System at 300 Montvue Road, Knoxville, Tennessee 37919.

2. Rite Aid

65. Defendant RITE AID HDQTRS. CORP. is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania. Defendant RITE AID OF TENNESSEE, INC. is a Tennessee corporation with a principal place of business in Knoxville, Tennessee. Defendant RITE AID OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC. is a Maryland corporation with its principal place of business located in Camp Hill Pennsylvania. Collectively, these entities are referred to as "Rite Aid."

66. Rite Aid self-distributed opioids to its locations in Tennessee. At all times relevant, Rite Aid has been licensed as a wholesaler/distributor in Tennessee.

67. Rite Aid can be served with process through its registered agent in Tennessee: CT Corporation System at 300 Montvue Rd., Knoxville, Tennessee 37919.

3. Walgreens

68. Defendant WALGREEN CO. ("Walgreens") is a Delaware corporation with its headquarters and principal place of business located in Deerfield, Illinois.

69. Walgreens self-distributed opioids to its locations in Tennessee. At all times relevant, Walgreens has been licensed as a wholesaler/distributor in Tennessee.

70. Walgreens can be served through its registered agent: Illinois Corporation Service Company, 801 Adlai Stevenson Drive, Springfield, Illinois, 62701.

4. Walmart

71. Defendant WALMART INC. (f/k/a Wal-Mart Stores, Inc.) is a multinational retail corporation incorporated in the State of Delaware. Defendant WAL-MART STORES EAST, L.P. is a Delaware corporation which holds the DEA registrations for its parent company's distribution centers. Collectively, these entities are referred to as "Walmart."

72. Walmart self-distributed opioids to its locations in Tennessee. At all times relevant, Walmart has been licensed as a wholesaler/distributor in Tennessee.

73. Walmart can be served with process through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919.

E. The Pill Mill Defendants

1. Timothy Abbott

74. Defendant TIMOTHY ABBOTT is a resident of Davidson County, Tennessee. He may be served with process at 3205 Louise Drive, Nashville, Tennessee 37211.

75. Abbott was a licensed podiatrist in Tennessee from 1986 until his license was revoked by the State of Tennessee in June 2020.

76. Abbott participated in the illegal drug market for opioids by running a pill mill in Davidson County, conduct which resulted in him pleading guilty to seven counts of unlawfully distributing opioids under the Controlled Substances Act.

2. Cindy Scott

77. Defendant CINDY SCOTT is a resident of Davidson County, Tennessee. She may be served with process at 3813 Moss Rose Drive, Nashville, Tennessee 37216.

78. Scott was a registered nurse and advanced practice nurse who was licensed in Tennessee from 2004 until she was placed on probation by the State of Tennessee in November 2016.

79. Scott participated in the illegal drug market for opioids by helping run pill mills in and around Davidson County, conduct which resulted in her being placed on probation by the State of Tennessee and being required to surrender her DEA registration by the United States Department of Justice.

3. Hemal Mehta and Heather Marks

80. Defendant HEMAL MEHTA is a resident of Williamson County, Tennessee who has been licensed to practice medicine in Tennessee since 2004. He has practiced medicine in the Nashville Metro Area, including practicing in Davidson County and treating Davidson County residents. He may be served with process at 1856 Longmoore Lane, Brentwood, Tennessee 37027.

81. Defendant HEATHER MARKS is a resident of Rutherford County, Tennessee who has been licensed as an Advanced Practice Registered Nurse in Tennessee since 2015. She has practiced medicine in the Nashville Metro Area, including treating Davidson County residents. She may be served with process at 315 E Clark Blvd, Unit J, Murfreesboro, Tennessee 37130.

82. Mehta and Marks participated in the illegal drug market for opioids by operating a pill mill in the Nashville Metro Area. Both Mehta and Marks were indicted on federal drug charges for the unlawful distribution and conspiracy to distribute oxycodone and oxymorphone.

4. James Maccarone

83. Defendant JAMES MACCARONE is a resident of Montgomery County, Tennessee who was licensed to practice medicine in Tennessee from 2007 until February 2022.

He operated a pill mill that issued opioid prescriptions that were filled in Davidson County. He may be served with process at 137 Clarendon Trace, Clarksville, Tennessee 37043.

84. Maccarone participated in the illegal drug market for opioids by operating a pill mill which issued opioid prescriptions that were filled in and around Davidson County. He pled guilty to conspiracy to unlawfully distribute opioids in violation of the federal Controlled Substances Act.

5. Pardue's Pharmacy

85. Defendant DEL MAR MEDICAL, INC. d/b/a PARDUE'S PHARMACY ("Pardue's") is a for-profit Tennessee corporation, which operates multiple pharmacy locations in Davidson County and the Nashville Metro area, including Pardue's Pharmacy at 1900 Patterson Street, Suite 200, Nashville, Tennessee 37203 (which it purchased in 2017 following the death of its original owner, Wendell Pardue). Pardue's is one of Davidson County's largest dispensers of opioids. Pardue's regularly engaged in suspicious ordering patterns and dispensed opioids for prescriptions written by notorious pill mill prescribers. Pardue's may be served with process through its registered agent: James M. Jackson, 198 E. Division Street, Mount Juliet, Tennessee 37122.

SCIENTIFIC BACKGROUND

A. Opioids Have Never Been Proven Appropriate for Long-Term Chronic Pain and Other Non-Acute Medical Problems

86. This case primarily, but not exclusively, concerns the following four types of opioids:

a. Oxycodone: Oxycodone is a powerful type of opioid. It can be prescribed as oxycodone or more specifically branded by a company, such as OxyContin or Roxicodone.

b. Hydrocodone: Hydrocodone is also a type of opioid. It can be prescribed as hydrocodone or more specifically branded by a company, such as Lortab or Vicodin.

c. Oxymorphone: Oxymorphone is also a type of opioid. It can be prescribed as oxymorphone or more specifically branded by a company, such as Opana and Opana ER.

d. Hydromorphone: Hydromorphone is also a type of opioid. It can be prescribed as hydromorphone or more specifically branded by a company, such as Exalgo.

87. The scientific consensus is that opioids such as these are dangerous, highly addictive, and inappropriate for long-term chronic pain – as opposed to cancer pain and pain associated with surgery and acute injuries. This opinion existed in the mid-1990s and has never been challenged in any meaningful way with new, valid scientific evidence.

88. The National Safety Council, a not-for-profit organization chartered by Congress to improve public health, has published a summary of research titled "Evidence for the Efficacy of Pain Medications."[11] The National Safety Council report concludes that "[d]espite the widespread use of opioid medications to treat chronic pain, there is no significant evidence to support this practice."[12]

89. Multiple researchers have found that "no evidence exists to support long term use—longer than four months—of opioids to treat chronic pain."[13]

90. A 2013 review of existing literature by Dr. Igor Kissin of the Department of Anesthesiology, Perioperative, and Pain Medicine at Brigham and Women's Hospital, Harvard

[11] Dr. Donald Teater, Nat'l Safety Counsel, *Evidence for the Efficacy of Pain Medications*, 3 (2014) (hereinafter Evidence for Efficacy).
[12] *Id.* at 6.
[13] *Id.* (citing multiple publications)

Medical School, concluded that "[n]ot a single randomized controlled trial with opioid treatment lasting [greater than] 3 months was found."[14]

91. The same review found that "[a]ll studies with a duration of opioid treatment [greater than or equal to] 6 months were conducted without a proper control group."[15]

92. Dr. Kissin further concluded that "[t]here is no strong evidence-based foundation for the conclusion that long-term opioid treatment of chronic malignant pain is effective."[16]

B. Opioids Carry a High Risk of Addiction, Serious Medical Problems, and Death

93. Opioids have severe side effects, including gastrointestinal bleeding, impaired recovery from injury or surgery, cognitive impairment, respiratory depression, endocrine abnormalities, hyperalgesia (increased sensitivity to pain), increased risk of fractures and hospitalization for the elderly, addiction, and death.[17]

94. Research based on actual patient interviews has found that, ***among patients who received four or more prescriptions in the prior year, 35% met the criteria for a lifetime opioid dependence, and 25.8% met the criteria for current opioid dependence***.[18]

95. Dr. Nora D. Volkow and Dr. Wilson M. Compton, the Director and Deputy Director of the National Institute of Drug Abuse at the National Institute of Health, respectively, co-authored a 2006 study that concluded: "[t]hough the use of opioid analgesics for the treatment of

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[14] Dr. Igor Kissin, *Long-term Opioid Treatment of Chronic Nonmalignant Pain: Unproven Efficacy and Neglected Safety?*, 2013:6 J. Pain Research 513, 513 (2013), available at https://www.dovepress.com/long-term-opioid-treatment-of-chronic-nonmalignant-painnbspunproven-ef-peer-reviewed-article-JPR.

[15] *Id.*

[16] *Id.*

[17] Dr. Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, 2-6 (2014) (summarizing side effect data). (hereinafter *Side Effects*).

[18] Joseph A. Boscarino, *Opioid-Use Disorder Among Patients on Long-Term Opioid TherapyI*, 2015:6 Substance Abuse and Rehabilitation 87, 87-89 (2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/.

acute pain appears to be generally benign, ***long-term administration of opioids has been associated with clinically meaningful rates of abuse or addiction***."[19]

96. Consistent with this finding, a 2011 review of medical and pharmacy claims records revealed that two thirds of patients who took opioids daily for ninety days were still taking opioids five years later.[20]

97. Researchers evaluating opioids for treatment following lumbar disc herniation likewise found that giving such patients opioids had no effect on treatment outcome, but significantly increased their risk for long term opioid addiction.[21]

98. Dr. Mitchell H. Katz, current President and CEO of the New York City Health and Hospitals (the largest public healthcare system in the United States), has described how patients with nonmalignant conditions can end up as drug addicts because of the prescribing of opioids:

> A certain number of patients get better with NSAIDs [non-steroidal anti-inflammatory drugs, like Tylenol]. For those still complaining of pain, you next prescribe a short-acting opioid with a relatively low potency, such as acetaminophen with codeine. ...You tell them about the adverse effects of opioids and encourage them to use the lowest dose necessary. Not infrequently, at the next visit they tell you that the medicine works but that they are taking the pills more frequently than directed. At this point, you worry about liver damage from the acetaminophen and switch to a higher potency, longer acting agent. The patient returns for follow-up visits and tells you that the pills work but that they sometimes take an extra pill and could you please increase the number so they "don't run out before the next visit." Before you know it, the patient is on a high dose of an opioid, and you are unsure whether you have actually helped them. ***What you know is you have committed yourself to endless negotiations about increasing doses, lost pill bottles, calls from emergency departments, worries that your patient is selling the***

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[19] Wilson M. Compton et al., *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Nat'l Inst. on Drug Abuse 103, 103-07 (2006) (emphasis added).
[20] Bradley C. Martin et al., *Long-term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) J. Gen. Intern. Med. 1450, 1450-57 (2011).
[21] Evidence for Efficacy at 5 (citing Radcliff et al., Does Opioid Pain Medication Use Affect the Outcome of Patients with Lumbar Disk Herniation?, 38(14) The Spine J. E849, E849-60 (2013)).

drugs, and the possibility that one day, your patient will take too many pills, perhaps with alcohol, and overdose.[22]

MATERIAL FACTS

A. Overview: The Defendants Created the Illegal Drug Market Through Unlawful Distribution and Otherwise Knowingly Supplied and Knowingly Participated in the Illegal Drug Market in Tennessee

99. The Drug Producer Defendants, Drug Distributor Defendants, Pharmacy Chain Defendants, and Pill Mill Defendants all participated in the illegal drug market in Tennessee and capitalized on it. Each played a knowing role in creating, perpetuating, and expanding the opioid crisis.

100. Controlled substances are, by definition, highly subject to abuse and diversion. For this reason, Tennessee regulates every participant in the chain of distribution. No one can distribute or dispense prescription opioids in Tennessee without maintaining effective controls against diversion and ensuring that the drugs are serving a lawful medical purpose. Indiscriminate distribution without sufficient controls is unlawful and can lead to criminal penalties in Tennessee.

101. The Drug Defendants, Distributor Defendants, and Pharmacy Chain Defendants have used their registration certificates with Tennessee as cover for what is essentially a criminal enterprise. They knowingly distributed drugs into Tennessee without diversion controls, conscious that they were feeding pill mills and the black market rather than legitimate medical need. That conduct was unlawful. Even in isolation, it subjects them to liability under the DDLA.

102. But the problem was much, much worse than that. The Producer Defendants purposely created the illegal market for their own products by successfully convincing prescribers to prescribe opioids in high volumes, high dosages, and with such frequency that the patients

[22] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Arch Intern. Med. 1422, 1422-24 (2010) (emphasis added).

quickly (and inevitably) would become addicted – as the Producer Defendants knew would happen. They devised every way imaginable to guarantee this result. This included lying to prescribers about the risk profile of their opioids, spreading disinformation about how addictive their drugs were, and targeting with surgical precision the highest-volume prescribers to convince them to prescribe more opioids – knowing that they were operating pill mills. They established direct relationships with pharmacies that supplied pill mills. They flooded small Tennessee communities with opioids at levels that their own experts determined were resulting in diversion – filling the very prescriptions that they convinced corrupt prescribers to make, to feed the addicts and pill seekers that they had addicted to their drugs. They hired large sales forces, rewarded them for doing business with pill mills, and penalized them for missing sales targets. When the government directed them to implement effective controls against diversion, they purposely created sham "suspicious order monitoring" programs that were structured to fail and structured to allow them to ship opioids into known diversion channels. This entire system was a criminal chain of distribution from start to finish.

103. The Drug Distributor Defendants and Pharmacy Chain Defendants also participated in this enterprise and abused their authority. They knew who the pill mill operators were and knew when the level of drugs into these communities was feeding the illegal drug market. But like the Producer Defendants, they purposely did not implement meaningful diversion controls, incentivized their employees to service pill mills, and reaped handsome profits from the flow of drugs into the black market. They distributed these drugs unlawfully, and otherwise knowingly facilitated illegal prescription opioids sales.

104. The Pill Mill Defendants also participated in the illegal drug market by issuing and filling prescriptions for no legitimate medical purpose.

105. At every step, these Defendants sought to stream drugs into the illegal market, to continue over-supplying Tennessee communities at levels that were not medically justifiable, and enjoy profits derived from the illegal distribution of opioids. They continue to do so to this day.

B. The Drug Producer Defendants, Distributor Defendants, and Pharmacy Chain Defendants Have All Participated in the Distribution Pipeline for Opioids in Tennessee and in the Baby Doe Plaintiffs' Community

1. The Drug Producer Defendants, Distributor Defendants, and Pharmacy Chain Defendants Possessed Information Reflecting Diversion by Prescribers and Pharmacies but Facilitated that Diversion Anyway

106. As described herein, the Drug Producer Defendants, Distributor Defendants, and Pharmacy Chain Defendants did not maintain effective controls against diversion, rendering their actions illegal, and they otherwise engaged in many other acts to facilitate diversion of their drugs illegally. They also plainly undertook actions in Tennessee or directed at Tennessee that they knew were detrimental to public health and safety.

107. The related crises of abuse and illegal diversion of prescription opioids in Tennessee is well-documented in a variety of publicly available sources. Indeed, the prescription statistics reflect how the Producer Defendants, Distributor Defendants, and Pharmacy Chain Defendants each are participating in the unconscionable flow opioids into Middle Tennessee.

108. Through their market research and extensive networks of sales representatives and face-to-face detailing of health care providers ("HCP"), The Drug Producer Defendants could, and did, observe signs of illegal diversion. The Drug Producer Defendants could, and did, observe signs of diversion, including:

- an HCP who has a disproportionate number of patients who pay cash for office visits and dispensed medications;
- an HCP with a sudden unexplained change in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or the practice type;

- an HCP's practice where unauthorized individuals are signing prescriptions or dispensing controlled substances;
- an HCP's practice where drugs or doses are not being individualized;
- an HCP with a lack of qualified staff, such as registered nurses or nurse practitioners;
- an HCP's practice with large numbers of patients who travel significant distances, for example, across state lines, to obtain and/or fill their prescriptions without rational explanation;
- an HCP's practice where there are reports that patients make frequent early requests for new prescriptions in advance; and
- an HCP who moves his or her practice from one state to another on more than one occasion within a couple of years without rational explanation.

109. The Drug Producer Defendants also received information from credible sources—including, but not limited to, pharmacists and law enforcement agencies—that an HCP or his or her patients were diverting prescription medications.

110. Upon information and belief, and as described further herein, the Drug Producer Defendants each maintained an internal database of HCPs suspected of inappropriately prescribing opioids. HCPs could be added to the database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills. In particular, the Drug Producer Defendants tracked HCPs' prescribing practices using data obtained from IMS Health, which allowed them to identify HCPs writing excessively large numbers of prescriptions, particularly for high doses, which is a potential sign of diversion and drug dealing.[23]

[23] Harriet Ryan, Lisa Girion, & Scott Glover, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drug Maker Knew*, L.A. Times, July 10, 2016, available at: https://www.latimes.com/projects/la-me-oxycontin-part2..

111. The Drug Producer Defendants also possess information called "chargeback" data from their distributors. As reported in the Washington Post, there is an "industry-wide practice" whereby pharmaceutical drug producers pay their distributors rebates and/or "chargebacks" on prescription opioid sales.[24] In return, the distributors provide the Drug Producer Defendants with downstream purchasing information, which allows them to track their prescription opioids down the entire supply chain, all the way to the retail level.[25]

112. Using chargeback data, the Drug Producer Defendants knew – just as the prescription opioid distributors and pharmacy chains knew – the volume, frequency, and pattern of prescription opioid orders being placed and filled. From that data, they knew or recognized which orders were suspicious and indicative of diversion in Tennessee and elsewhere. However, they continued to fill orders relative to those accounts (including pharmacies and dispensing physicians) for their drugs, despite knowing that the orders were suspicious and indicative of diversion, that the pharmacies to whom the orders were shipped were engaging in suspicious practices indicative of diversion, and that the pharmacies were filling orders from pill mills and other high-volume prescribers engaged in suspicious prescribing practices. To make matters worse, the Producer Defendants used this chargeback data for sales purposes to identify the highest volume prescribers and highest-volume pharmacies as sales targets. Many of these targets were located in Tennessee communities with a thriving illegal drug market and an obvious over-supply issue. In this way, the Producer Defendants knowingly facilitated the illegal diversion of prescriptions by (inter alia) suspicious prescribers and pharmacies, enabled the illegal diversion of

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24 Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Wash. Post, April 2, 2017, available at: https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/

25 *Id.*

prescription opioids, aided criminal activity, and otherwise facilitated the dissemination of massive quantities of prescription opioids into the black market.

113. Tennessee regulates the distribution of controlled substances. Under Tennessee law, prescription opioids are "Schedule II" controlled substances because they inherently have a "high potential for abuse" and that "may lead to severe psychic or physical dependence."[26] For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must register with the State and must ensure that the drugs are only being distributed to serve legitimate medical purposes.[27] If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee. Indeed, entities holding a Tennessee license can be criminally prosecuted for violating their responsibilities in the distribution chain.[28] Defendants violated these preconditions and acted unlawfully.

2. Allergan Knowingly Participated in Tennessee's Illegal Drug Market

114. Allergan was one of the two largest manufacturers of generic opioids. Because Allergan lacked a meaningful suspicious order monitoring program, its opioids flooded the market without pause, worsening the opioid epidemic.

115. Allergan's promotional spending on opioids, which was virtually nonexistent in the 2004-2008 period, began to sharply rise in 2009, when it began marketing Kadian. The third quarter of 2011 saw a peak of $3 million and nearly $7 million for the year.

[26] Tenn. Code Ann. § 39-17-407.
[27] *See, e.g.*, Tenn. Code Ann. § 53-11-302, -303 *and* Rules of Tenn. Bd. Of Pharmacy, Ch. 1140-02.01 *et seq*, 1140-09.01 *et seq*.
[28] *See* Tenn. Code Ann. § 53-11-401(a).

116. To ensure that these messages reached individual physicians, Allergan deployed sales representatives to visit HCPs in Tennessee and across the country. Allergan chose its detailing targets based on the likelihood of higher numbers of prescriptions at higher doses, with no consideration as to the risk of misuse. Allergan carefully tracked the prescription trends of the HCPs whom it detailed.

117. Allergan trained its sales representatives to deceptively minimize the risk of addiction by: (1) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (2) emphasizing the difference between substance dependence and substance abuse; and (3) promoting the unsupported term "pseudoaddiction."

118. Allergan misleadingly instructed its sales team that opioid doses could be escalated during long-term opioid therapy, without hitting a dose ceiling, which purportedly made them safer than other forms of therapy such as acetaminophen or NSAIDs.

119. Allergan also actively marketed its generic drugs. Prior to the sale of its generic business to Teva, Allergan's marketing strategy included promotion of its generic opioids, including generic Kadian (morphine sulfate), directly to HCPs. Allergan sales representatives received bonuses for both branded and generic Kadian sales, and used the same selling points for both versions of the drug, available in many leading pharmacies, advertising that the generic had the same features and benefits as the branded product.

120. Allergan also promoted its generic Opana ER (oxymorphone ER). Allergan saw a business opportunity due to Endo discontinuing certain dosages and Endo production issues, and began training and deploying the Kadian sales force to detail doctors to promote generic Opana ER. Allergan also paid bonuses to its sales team for meeting sales goals for generic Opana ER.

121. Allergan also promoted its generics through direct mail and email campaigns and journal advertisements aggressively marketed its generic opioids through its distributors, in particular Distributor Defendant McKesson. To promote Allergan's generic oxymorphone ER, oxycodone, and generic morphine sulfate, McKesson deployed a variety of tactics, including notifying pharmacies about the products using Allergan talking points and posting sell sheets on its website. McKesson had an incentive to maximize Allergan's opioid sales because it received a rebate through its "OneStop" sales program if it achieved a certain sales volume.

122. Allergan similarly collaborated with Distributor Defendants Cardinal and ABC to promote Allergan's generic opioids through targeted telemarketing and direct mail campaigns aimed at pharmacies. Allergan collaborated with ABC in an initiative to drive generic conversion at a faster rate than what would occur without its intervention.

123. Allergan also worked with Walgreens to send a letter to patients who had filled a prescription for Opana ER within the prior year, informing them that although Endo no longer manufactured certain dosages of Opana ER, a generic was now available from Allergan.

124. Through its aggressive marketing, Allergan expanded the market for opioids in Tennessee. Allergan compounded this harm by failing to put in place appropriate procedures to ensure that suspicious orders—orders of unusual size, frequency, or those deviating from a normal pattern—would be reported to governmental authorities as required by law. Instead, Allergan continued to supply far more opioids than were justified, flooding the Tennessee market.

125. As an entity registered with the DEA and the Tennessee Board of Pharmacy, Allergan knew it was required to maintain effective controls against diversion of opioids and to report suspicious orders.

126. Allergan possessed ample sources of data that allowed it to detect and report suspicious orders of opioids, both from its direct and indirect customers. The company's sales representatives regularly visited pharmacies and HCPs to promote Allergan's products, which allowed them to observe red flags of diversion.

127. Despite these available sources of information regarding potential diversion, Allergan failed to properly design and operate a system that would be capable of detecting suspicious opioid orders. Prior to 2011, any process that Allergan had that could be considered an opioid order monitoring system was not even properly automated. After 2011, Allergan finally began to acknowledge its responsibility to create an opioid order monitoring system, but the procedures it put in place were severely lacking, and were focused on approving—not restricting—orders of excessive quantities of opioids.

128. To the extent Allergan established thresholds to detect suspicious orders, they were wholly inadequate. Allergan also adjusted and otherwise manipulated its thresholds so that it could ship its opioid products without any obstacles.

129. Allergan failed to perform appropriate due diligence on its customers, both generally and at the time it should have been alerted to a suspicious order. Instead of independently investigating customers and the reasons behind suspicious orders, Allergan reached out to customers and simply asked them to provide a justification for large orders. Allergan even required customers to provide a reason for reduced orders.

130. Allergan failed to stop shipments after it knew or should have known that opioid orders remained suspicious, had no requirement to stop shipments on suspicious indirect sales, and failed to report suspicious orders to the DEA. Eventually, Allergan ceased operating any suspicious order monitoring program at all, when it "outsourced" those duties to a distributor.

131. Allergan failed to discontinue detailing HCPs who were suspected of diversion. On the contrary, Allergan chose its detailing targets based on the likelihood of higher numbers of prescriptions.

132. Allergan knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Allergan is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Allergan knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Allergan's products. Allergan also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of its products to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

133. Also, Allergan knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing of prescription opioids; and (iii) permitting and directing sales representatives to visit prescribers whose were engaging in suspicious conduct.

3. Endo Knowingly Participated in Tennessee's Illegal Drug Market

134. Endo continues to participate in an illegal drug market that it helped create.

135. The original version of Opana ER, which was known by the street names "stop signs," "the O bomb," and "new blues," is typically crushed by addicts and either snorted or

injected.[29] "Crushing defeats the pill's 'extended release' design, releasing the drug all at once."[30] This type of Opana abuse is particularly dangerous "because [Opana] is more potent, per milligram, than OxyContin, and users who are not familiar with how strong it is may be vulnerable to overdosing."[31]

136. Endo introduced Opana ER in 2006. For the next several years, it endeavored to capture market share and cut into the OxyContin market. As with the other defendants, Endo actively marketed to the highest volume prescribers of extended release opioids.

137. In July 2012, USA Today reported that Original Opana ER had overtaken OxyContin as the drug of choice for prescription opioid addicts.[32]

138. The USA Today article began by recounting how, in 2012 alone, there had been 11 pharmacy robberies in Fort Wayne, Indiana (a city of only 250,000 people), and "[i]n almost every case, the robbers asked specifically for Opana."[33]

139. The article went on to explain that "the Opana problem grew swiftly and sharply, particularly in several states where prescription drug abuse is deeply engrained." Among the states experiencing a dramatic increase in Opana ER abuse, the article listed the following:

- "Nassau County, N.Y. issued a health alert in 2011 when the New York City suburb saw the first signs of an alarming spike in Opana use. Medicaid data for the county showed prescriptions for extended-release Opana had increased 45% in six months."[34]

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[29] Mary Wisniewski, Painkiller Opana, new scourge of rural America, Reuters (Mar. 26, 2012). Available at: https://www.reuters.com/article/us-drugs-abuse-opana/painkiller-opana-new-scourge-of-rural-america-idUSBRE82Q04120120327. (hereinafter "Wisniewski, Painkiller Opana, new scourge").
[30] *Id.*
[31] *Id.*
[32] Donna Leinwand Leger, Opana abuse in USA overtakes OxyContin, USA Today (July 11, 2012). Available at: http://usatoday30.usatoday.com/news/nation/story/2012-07-10/opana-painkiller-addiction/56137086/1. [hereinafter "Leger, Opana Abuse"]
[33] *Id.*
[34] *Id.*

- "A DEA intelligence briefing noted increases in Opana [use] in Pennsylvania, including Philadelphia, and Delaware. In New Castle, Del., the DEA said, drug users had switched from uncrushable OxyContin to the crushable oxymorphone 'for ease of use,' pushing the price for a 40 mg tablet to $65. A tablet costs $4 to $8 when purchased legitimately at a pharmacy." [35]

- "In Ohio, authorities in Akron, Cincinnati and Athens noted surges in Opana as a replacement for OxyContin, the state's Substance Abuse Monitoring Network reported earlier [in 2012]. . . . Opana 40 mg tablets sell for $60 to $70 each, outpacing the once-popular old formulation OxyContin, which now sells for at least $1 a milligram, the report said."[36]

140. The spike in Opana ER abuse and diversion was particularly pronounced in Tennessee's neighbor to the north, Kentucky.[37] In 2010, toxicology tests identified oxymorphone, the key ingredient in Opana ER, in 2% of Kentucky's overdose death cases, according to the Kentucky Office of Drug Control Policy.[38] By 2011, oxymorphone was present in the blood of 23% of overdose victims in the state.[39]

141. In 2011, the drugs most frequently found in overdose victims in Kentucky broke down as follows: Alprazolam (Xanax) – found in 286 overdose victims; Oxycodone (OxyContin) – found in 213 overdose victims; Hydrocodone (Vicodin) – found in 187 overdose victims; and oxymorphone (Opana ER) – found in 154 overdose victims.[40]

142. Another 2012 news article, this one by Reuters, further highlighted the "Opana problem [that] has been reported by abuse experts around the country."[41] As evidence of the "Opana problem," the Reuters' article pointed to Florida, where "the number of oxymorphone-

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[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] Mary Wisniewski, *Painkiller Opana, New Scourge of Rural America*, Reuters, March 26, 2012, available at Painkiller Opana, new scourge of rural America | Reuters

related deaths rose to 493 in 2010, an increase of 109 percent from the previous year."[42] Additionally, the article specifically referenced the fact that "users and dealers get painkillers from so-called 'pill mills' – storefront pain clinics that sell drugs for cash up front, often to out-of-state buyers who take them for resale."[43]

143. Of particular note, the 2012 Reuters article also quoted Detective Michael Donaldson – a Nashville, Tennessee detective who saw an increase in Opana abuse in the state – who said that "many small towns have 'dirty doctors' willing to give out unneeded prescriptions."[44]

144. As seen across the country, diversion of reformulated Opana ER was rampant in Tennessee following its introduction to the market. In October 2012, the CDC issued a health alert, saying a "cluster of at least 12 patients" (later raised to 15 victims) in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana.[45] These incidents immediately provided a clear and unmistakable signal to Endo that the "abuse-deterrent" formulation of Opana ER in fact was highly susceptible to intravenous abuse, which both Endo and the FDA considered to be a far more dangerous form of abuse than insufflation.

145. Furthermore, following the release of reformulated Opana ER, Hawkins County law enforcement officials told Endo that they were "overwhelmed by Opana abuse in their area." They told Endo that local doctors were writing prescriptions to prescription drug abusers, that they

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[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] Tom Dreisbach, *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, NPR – All Things Considered (Apr. 1, 2016). Available at: https://www.npr.org/sections/health-shots/2016/04/01[redacted]how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

had arrested and convicted multiple doctors for writing fraudulent prescriptions for drug traffickers, and that three people had died from a "suspect doctor" who opened a pain clinic in the area. Endo even interviewed one of the TTP victims, where it learned that abusing reformulated Opana ER by boiling and then injecting it was also occurring in nearby Johnson City and Kingsport. Despite receiving this clear safety signal, Endo nevertheless continued to call on Tennessee prescribers and distribute Opana ER not only in upper East Tennessee where the crisis erupted, but throughout the state.

146. During the same time frame, Endo commissioned an internal report which stated that, in light of the non-availability of original OxyContin, Opana ER had become the key drug of choice for abusers and addicts. Endo also quickly recognized that higher injection rates (i.e., intravenous abuse) were occurring in Tennessee. Indeed, in 2012, Endo acknowledged under oath that, following the introduction of reformulated OxyContin in August 2010, abuse of Opana ER spiked because drug users found that it was easier to snort or inject. This transfer of addicts and abusers from OxyContin to Opana ER was called the "squeezing the balloon" effect.[46] Endo nevertheless continued to detail Tennessee prescribers.

147. Indeed, when an "abuse-deterrent" form of OxyContin in 2012, Endo recognized that pill seekers and other drug abusers were finding OxyContin more difficult to abuse, and that those drug abusers were turning to Opana ER because it was easy to crush and snort. Perceiving this "squeeze the balloon" effect, Endo consciously endeavored to capture the market share that OxyContin was losing as addicts turned away from OxyContin and sought out an alternative to abuse.

[46] Collins PI Declaration ¶ 9.

148. In connection with its unsuccessful petition to have reformulated Opana ER designated as tamper-resistant, Endo publicly advocated that its original formulation of Opana ER was so dangerous and susceptible to abuse and diversion that it should be taken off the market.[47] Endo represented, inter alia, that its own testing shows that "96% of research subjects were willing to snort the Original Formulation (which could be crushed into powder)."[48] It argued that allowing the Original Formulation onto the market "will result in increases in drug abuse, misuse and diversion," and that "[s]erious and predictable public harm would flow from entry and continued sale" of that product. Moreover, Endo acknowledged under oath that, following the introduction of reformulated OxyContin in August 2010, abusers turned to Opana ER as a drug that was easier to snort or inject.[49]

149. Thereafter, Endo sued the FDA, seeking a preliminary injunction to prevent generic versions of the original Opana ER from coming onto the market. It represented to a federal court as follows:

> Unless the Court intervenes and issues an injunction to preserve the status quo, on January 1, 2013, a generic version of the Original Formulation drug will be released. If this occurs . . . the public interest will be substantially and irreparably injured by release of generic versions of a drug which relies upon a drug that was withdrawn for safety reasons and that is subject to abuse and misuse that FDA acknowledges and against which it has long fought.
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> [***]
>
> Unless the Court intervenes and issues a preliminary injunction, there is a significant risk that a readily crushable, and thus admittedly less safe, opioid drug

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[47] https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html; *see also Endo Pharm. v. U.S. Food & Drug Admin., et al.,* Civil Action No. 1:12-cv-01936-RBW (Dkt. No. 5-1), Memo in Support of Motion for Preliminary Injunction, at 13 (stating that Endo represented to the FDA that permitting a generic manufacturer to introduce a generic equivalent to the original Opana ER "would allow abuse or diversion to continue . . . .").

[48] *Id.* at 14.

[49] Collins PI Declaration ¶ 9.

> will serve as the RLD for generic drugs that will then be subject to abuse and misuse. FDA inaction will have facilitated precisely the type of harm to the public interest against which it has fought for many years.[50]

Endo also argued that introducing the generic equivalent "***will result in drug abuse, misuse and diversion with a predictable upsurge in serious injuries and overdose deaths***."[51]

150. Thus, in 2012, Endo publicly acknowledged that it knew that original Opana ER was highly susceptible to abuse and diversion, that it was such a threat to public health and safety that neither it nor any equivalent should be allowed on the market, that diversion and adverse public health effects (including "serious injuries and overdose deaths") are "predictable" consequences of producing and distributing opioids that are subject to abuse. However, even as Endo was arguing that original Opana ER would harm people, it continued to distribute original Opana ER throughout the country for the next 9 months, including in Tennessee. Once the stores were exhausted, Endo then voluntarily removed that original formulation of Opana ER on the basis of those stated safety concerns.

151. In a conference call with investors on February 28, 2013, Endo officials were asked about the reports of injection abuse, specifically those in Tennessee.[52] On that call, Ivan P. Gergel, Endo's chief scientific officer at the time, said: "We've designed the Opana crush-resistant formulation to be crush-resistant, to avoid primarily the nasal root of abuse. . . . Clearly, we are looking at this data . . . but it's in a very, very distinct area of the country."[53] Endo clearly knew that addiction and abuse of Opana ER was centered in Tennessee. It could have stopped calling on doctors in Tennessee and stopped filling orders for Opana ER intended for distribution in

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[50] *Endo Pharm. v. U.S. Food & Drug Admin., et al.*, Civil Action No. 1:12-cv-01936-RBW (Dkt. No. 5-1), Memo in Support of Motion for Preliminary Injunction, at 3.
[51] *Id.* (emphasis added).
[52] *Id.*
[53] *Id.*

Tennessee to stop the abuse and diversion. Instead, it chose to continue to call on Tennessee prescribers, particularly its highest volume prescribers. And it continued to push pills on prescribers and market Opana ER in Tennessee the same way as the rest of the country: Tennessee representatives received the same instructions relative to Tennessee prescribers as everywhere else.

152. Endo's sales department received IMS Health data that identified the volume of Opana prescriptions written by particular providers in Tennessee. Endo reviewed these reports regularly. It used that data to target physicians to prescribe more Opana ER.

153. Later, in 2014, a case study from the University of Tennessee School of Medicine described the university-based hospital's experience of a series of ten patients with characteristic clinical and laboratory findings of Thrombotic Microangiopathy (TMA) and documented recent history of illicit intravenous Opana ER use.

154. Endo itself recognized abuse and diversion of Opana ER in Tennessee was especially acute in Tennessee. Endo collected information from multiple sources reflecting the incidence of abuse of Opana ER in Tennessee relative to other drugs and the source of those drugs. Based on that data, in March 2017, Endo's Chief Medical Officer, Neil Shusterman acknowledged to the FDA in March 2017 that ***75% of all abuse of reformulated Opana ER occurred in Tennessee*** over the post-monitoring period for reformulated Opana ER, even though Tennessee has just 2% of the nation's population. Shusterman also acknowledged that "while Endo was receiving quarterly surveillance reports in real-time, NAVIPPRO informed us ***that a continually increasing proportion of Opana ER cases was coming from Tennessee***."[54] In fact, Tennessee's

[54]Transcript of March 13, 2017 FDA Hearing at pg. 71 (emphasis added), accessible at http://web.archive.org/web/20211129144636/https://www.fda.gov/media/104539/download.

abuse rates were so high that Endo chose to exclude them from its nationwide calculations. Dr. Shusterman presented an alarming picture of acute problems with Opana ER and other opioids in Tennessee:

a. Relative to the rest of the country, rates of Opana ER injections in Tennessee were exceptionally high for oxycodone immediate release, morphine extended release, and OxyContin before 2012. Endo stated that there was "clearly an intravenous abuse issue in Tennessee that goes beyond Opana ER[.]"

b. Intravenous abuse of Opana ER increased by approximately a factor of three after the reformulation in 2012.

c. Following the reformulation, injection abuse of Opana ER in Tennessee increased.

d. Tennessee had an "uncommonly high abuse" not only for Opana ER, but also for many other opioids.

e. The data indicated that Tennessee drug abusers who needed substance treatment "might be a more severe group of opioid abusers with more intravenous experience than those in other states."[55]

f. Endo therefore noted a special "effect of Tennessee," which "warrants that the two regions be looked at separately."[56]

g. Endo acknowledged that rates of IV abuse in northeast Tennessee "have been documented for a long time." [57]

h. Tennessee had "abuse prevalence an order of magnitude higher than in other parts of the United States, and increased intravenous abuse of all opioids, particularly Opana ER."[58]

i. Tennessee had a special "abuse psychology."[59]

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[55] *Id.* at 77.
[56] *Id.*
[57] *Id.* at 91.
[58] *Id.* at 100.
[59] *Id.* at 132.

j. When asked by the FDA whether Endo could "determine how many tablets of oxymorphone that you ship to a specific area in a given year," Endo responded: "Absolutely."[60]

155. Like the other defendants, Endo employed a sales force that specifically targeted high-volume opioid prescribers to convince them to prescribe more Opana ER or to prescribe it instead of OxyContin, as well as to prescribe Endocet and other branded Endo drugs. Endo identified these high-volume prescribers as the softest targets. Like other defendants, it compiled data showing which prescribers issued the most opioid prescriptions and detailed those prescribers repeatedly, including prescribers in Tennessee and in Plaintiffs' community. As with the other producer defendants, Endo recognized that detailing doctors drives prescriptions, and it provided volume-based bonuses or commissions to sales representatives. Endo's detailing efforts were successful. Opana ER sales rose, and the vast majority of prescriptions for Opana ER came from doctors that Endo detailed. The same holds true as to Endo's other branded opioids.

156. Endo knew that supplying large quantities of opioids to a region necessarily correlates with increased rates of abuse and diversion. In other words, it knew that the more opioids are available in a given area, the more they will be abused. For example, in 2014, its Risk Management analyzed Inflexxion data and determined that "[t]he number of prescriptions dispensed within a geographic region is related to a product's potential diversion and abuse." Endo also determined that the level of prescriptions dispensed for reformulated Opana ER in Tennessee was among the highest among states within the dataset that Endo was analyzing.

157. Endo also recognized that the vast majority of opioids that are abused originate with prescriptions from a healthcare provider, as opposed to another source (pharmacy theft, etc.). Endo recognized that there was an illegal market for its products and knew that supplying Opana ER

[60] *Id.* at 133.

and other prescription opioids would cause diversion to addicts. Endo knew that Opana ER became the opioid of choice for abusers in Tennessee. Nevertheless, it continued to push pills on the most dangerous, highest-volume prescribers and to encourage them to prescribe more Opana ER, knowing by doing so it would result in its drugs reaching the illegal drug market in increasing volumes.

158. In fact, Endo recognized that even legal, non-fraudulent opioid prescriptions constitute diversion when a naïve doctor willingly writes prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale. In other words, even as to prescribers did not know any better, Endo recognized that writing scripts for pill seekers and abusers was a form of diversion. Endo knew that this form of diversion was occurring in Tennessee and in Plaintiffs' community at alarming rates, and that any effort to convince those doctors to prescribe more opioids would cause increased diversion. It nevertheless continued to push pills on these prescribers, convincing them to prescribe more Opana ER despite knowing that this would result in further abuse and diversion in Tennessee – which had an acute abuse and diversion problem that Endo itself recognized.

159. Both before and after the reformulation of Opana ER, Endo pushed Opana ER to Tennessee prescribers who were operating pill mills, some of whom eventually were indicted. Endo actively pushed Opana ER on these prescribers even after receiving reports of suspected criminal activity.

a. For instance, in 2007, Endo received word from a district manager questioning whether Dr. Frank McNeil's practice was legitimate. The district manager indicated that Dr. McNeil was prescribing 80-100 scripts per week for extend release opioids, that 90% of his scripts were for OxyContin (i.e., one product), that he was not actually seeing patients regularly, had physicians' assistants who rotated through the office every 6 months, that he was receiving cash for OxyContin from "a lot" of his patients, and was prescribing OxyContin at a level that "seems almost

impossible even for a pain clinic." Endo nevertheless told the district manager that Endo could continue to call on that prescriber, noting internally that Dr. McNeil was responsible for 20% of the sales volume within one of Endo's sales territories. As described herein, in 2018 Tennessee ultimately stripped Dr. McNeil's medical license.

b. Endo also facilitated diversion by Dr. Mohamed in Morristown. After successfully courting Dr. Mohamed and convincing him to prescribe more Opana ER, Dr. Mohamed informed him that his "patients" could not fill their Opana ER prescriptions because the pharmacies had run out. Essentially, he had written so many scripts that local pharmacies ran out of sufficient supply to meet them. Endo then contacted numerous other local pharmacies and Endo's distributors in an effort to stock those pharmacies to fill Dr. Mohamed's prescription and make up for the shortage. Dr. Mohamed was Endo's highest prescriber in Tennessee. Endo never formally identified Dr. Mohamed as a suspicious subscriber.

These are just representative examples.

160. Endo sales representatives also called on pharmacies to ensure that the pharmacies stocked Endo products.

161. In 2011, the FDA directed Endo to conduct a post-marketing epidemiological study concerning the abuse deterrence potential of reformulated Opana ER. Endo conducted a study and learned through NAVIPPRO reports that Opana ER reformulated during the study period was procured for abuse primarily nationwide through drug dealers, at a rate 12 to 15 times higher than the national average for prescription drug abuse. As Endo later acknowledged to the FDA in March 2017, the same reports showed that abuse of Opana ER in Tennessee was multiple orders of magnitude higher than the rest of the country.

162. Endo tried to convince the FDA that patterns of abuse would be different and lower with the reformulated version. However, it turned out that reformulated Opana ER resulted in higher rates of intravenous abuse because of the specific chemical properties of the drug. This led to outbreaks of Thrombotic Microangiopathy, Hepatitis C, and HIV. Within three months of the reformulation hitting the market in 2012, Endo learned about the spike in intravenous and the

associated outbreaks. Despite such troubling reports of its newly-reformulated Opana ER product being abused intravenously, internally Endo's sales team was being told with respect to their detailing that it was "business as normal." Indeed, four years after first receiving reports of TTP from abuse of the newly-formulated Opana ER in Tennessee, Endo executives were discussing the fact that they had not yet solved "the intravenous issue."

163. Endo had evidence that 10% of prescriptions nationwide were coming from East Tennessee, even though that region has less than 0.7% of the nationwide population. This disproportionately included small communities, such as those in the larger Baby Doe Plaintiffs' community area, where there were far more prescriptions than people, a pervasive illegal drug network for prescription opioids (which included both pharmacies and prescribers who were engaged in criminal conduct and unlawful practices concerning prescription opioids), and high rates of addiction, NAS deaths, and overdose deaths.

164. During the same time frame that Endo reformulated Opana ER was being acutely abused and diverted in Tennessee, Endo engaged in a lobbying campaign to have Tennessee exclude a competing generic version of the drug (which was not "tamper resistant") from the market, and characterized Tennessee as a "critical" state for sales and marketing purposes that Endo needed to "win" in order for Opana ER to be successful. Essentially, at the same time that Endo identified that reformulated Opana ER was being abused intravenously in Tennessee at exceptionally high rates relative to the rest of the country, Endo simultaneously was targeting Tennessee as a "critical" and "key" state where it needed to drive more sales. In service of that goal, it engaged in a multi-pronged effort to drive sales of reformulated Opana ER, including targeting high-volume prescribers, including physicians, nurse practitioners, and physicians assistants, and "selling" the benefits of reformulated Opana.

165. Indeed, by 2014, the problem with Opana ER abuse and diversion in Tennessee had gotten so bad that Endo's President internally considered whether to close off distribution of Opana ER entirely. Endo recognized that its drugs were being abused and diverted at such volumes that stopping distribution entirely was warranted. However, Endo never took that step. Instead, it continued to flood Tennessee with Opana ER so as not to lose sales revenue. Indeed, during the same time frame, Endo was actively pushing Opana ER on the highest volume Tennessee prescribers who were pushing pills into the illegal drug market in alarming quantities. As of early 2014, 7 of Endo's top 20 prescribers were located in Tennessee, including prescribers in Knoxville, Nashville, and Memphis. Endo also identified the top OxyContin prescribers and directed its sales force to target them to prescribe a larger share of Opana ER.

166. Endo knew that it had a responsibility to monitor and report suspicious orders. Nevertheless, it implemented a system for detecting and reporting that was designed to fail. Endo utilized a structure that encouraged sales representatives to call on pill mill prescribers or over-prescribers and that, by the same token, disincentivized those representatives from reporting suspicious practices. Sales representatives had an inherent conflict of interest because reporting their customers would reduce their compensation. By the same token, Endo did not penalize any sales representatives for having supplied a suspicious prescriber. Furthermore, Endo's Chief Medical Liaison believed that sales personnel were not qualified to detect and report signs of abuse and diversion, and should not have been involved in that important function. Nevertheless, Endo entrusted the sales force to be only source of abuse detection and reporting for Endo. Not surprisingly, sales representatives did not report a single instance or abuse or diversion by a Tennessee prescriber. Nor, for that matter, did Endo classify an order from a distributor as suspicious.

167. Relative to Tennessee, ***it filled every single order ever submitted to it*** and continued to push Opana ER and other dangerously addictive pills on the highest-volume prescribers essentially no matter what information it learned.

168. Endo knowingly facilitated downstream diversion of its products and participated in Tennessee's illegal drug market for opioids. Its effort resulted in rampant abuse and diversion of Opana ER nationwide, in Tennessee, and in Baby Doe Plaintiffs' community.

169. The ongoing, and excessive, abuse of Opana ER reached such a critical level that, on June 8, 2017, the FDA took the unprecedented step of demanding that Endo permanently remove the drug from the marketplace.[61] According to a FDA press release, the agency's "decision [was] based on a review of all available post marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation."[62] The FDA further stated that its decision to remove the opioid from the marketplace followed a March 2017 FDA advisory committee meeting where a group of independent experts voted that "the benefits of reformulated Opana ER no longer outweigh its risks."[63]

170. On July 6, 2017, Endo announced that it would voluntarily remove Opana ER from the market, citing the FDA's concerns of diversion.[64]

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[61] FDA Press Release. FDA requests removal of Opana ER for risks related to abuse. June 8, 2017. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[62] *Id.*
[63] *Id.*
[64] CBS News online. Opana ER opioid painkiller pulled from the market by FDA request. July 7, 2017. Available at: https://www.cbsnews.com/news/drug-opana-er-opioid-painkiller-pulled-from-the-market-by-fda/ (last visited Dec. 1, 2021).

171. Despite evidence of widespread abuse, Endo continued to push its drug into the addiction pipeline in Tennessee, including Baby Doe Plaintiffs' community, with its highly addictive, and deadly, prescription opioid, all the while knowing that it was being diverted into the illicit market. From September 2015 through August 2017, Endo's Opana ER and Endocet were the second and third most-prescribed branded opioids throughout Tennessee, respectively, following only OxyContin.[65]

172. Furthermore, after the new Opana ER formulation was removed from the market at the FDA's request in July 2017, Endo pivoted and entered into a contract with Impax to share profits from sales of a generic equivalent to the original Opana ER sold under the "Impax" name. The agreement allows for profit-sharing for the next 11 years, starting January 1, 2018. As numerous observers have pointed out, "Endo is profiting off of the very drug it said was unsafe to stay on the market."[66] By Endo's own admission, continuing to distribute this product "will result in increases in drug abuse, misuse and diversion," along with "serious and predictable public harm." Accordingly, Endo has known all along that streaming its opioid products into communities "predictably" results in high levels of addiction, overdose death, and illegal diversion – but it does not care, so long as it continues to turn a profit.

173. Endo knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Endo is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Endo knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Endo's products. Endo also knowingly participated in the illegal drug market in the Baby Doe

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[65] Quintiles IMS Data.

[66] https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html.

Plaintiffs' community by supplying quantities of its products to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein. Endo also knowingly and illegally distributed both branded and generic opioids, including but not limited to operating without effective controls against diversion and filling suspicious orders.

174. Also, Endo knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing of prescription opioids; and (iii) permitting and directing sales representatives to visit prescribers whose were engaging in suspicious conduct.

4. J&J Knowingly Participated in Tennessee's Illegal Drug Market

175. J&J manufactures, markets, sells, and distributes the following opioids in Davidson County, in Tennessee, and nationwide: Duragesic (fentanyl patch), Nucynta ER (tapentadol hydrochloride), and Nucynta (tapentadol hydrochloride), both of which are Schedule II narctoics.

176. J&J introduced Duragesic in 1990. It is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." After seeing the success of OxyContin for chronic non-cancer pain, J&J re-launched Duragesic for chronic non-cancer pain as well.

177. J&J also marketed Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution, and indicated for the "relief of moderate to severe

acute pain in patients 18 years of age or older. J&J also marketed Nucynta ER ,which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of…pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults."

178. J&J instructed sales representatives in Davidson County, in Tennessee, and nationwide to market Duragesic as having better efficacy, better tolerability, and better patient compliance because it was a patch instead of a pill. These sales representatives were instructed to tell doctors that the patch provided better control in the event of patient opioid abuse because patients could not increase the patch dosage. However, sales representatives were aware of patients who increased the dosage by applying more than one patch at a time and were also aware that some patients abused the patch by freezing then chewing on it.

179. These dishonest and amoral sales tactics extended to J&J's promotion of Nucynta, wherein J&J trained its sales representatives to avoid the so-called "addiction ditch"—i.e., to avoid the negatives (addiction) and emphasize the positives (supposed efficacy) in sales calls—and to use a study from Dr. Portenoy "to create dialogue about Opiophobia as a barrier."

180. J&J further trained their sales representatives that there was a 2.6% or lower risk of addiction when using opioids prescribed by a doctor. As part of this same training, J&J trained its sales representatives to "establish that moderate to severe acute pain continues to be undertreated."

181. However, J&J did not provide its sales force with any training on opioid addiction. Instead, J&J sales representatives were rewarded with bonuses for targeting high-volume opioid

prescribers, several of whom were later indicted or convicted for illegal prescribing of controlled substances.

182. As part of its "pain management franchise" from the 1990s through at least 2016, Johnson & Johnson wholly owned Tasmania Alkaloids Limited ("Tasmania Alkaloids"), which was based in Tasmania and cultivated and processed opium poppy plants to manufacture narcotic raw materials to be imported into the U.S. to be processed and made into active pharmaceutical ingredients ("APIs") necessary to manufacture opioid drugs. It also wholly owned Noramco, Inc. which is based in Athens, Georgia and imported the raw narcotic materials produced by Tasmania Alkaloids, processed the materials into APIs, then sold the APIs to other opioid manufacturers in the U.S. J&J, through these subsidiaries, supplied the following APIs to other drug manufacturers in the U.S.: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone. J&J had supply agreements to sell controlled substance API with all 7 of the top U.S. generic companies as we as many of the top branded opioid producers.

183. Through its sales force, J&J had visibility, on both macro and micro levels, of how rampantly overprescribed branded and generic opioids and that they were ending up on the black market; however, J&J continued supplying these materials to opioid producers which helped fuel the illegal opioid market.

184. Additionally, J&J failed to design and operate a system to monitor suspicious orders of controlled substances and failed to notify the appropriate DEA field division of suspicious orders. They also failed to report the sales of drugs subject to abuse.

185. J&J knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. J&J is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. J&J knew that such inflated

prescribing necessarily reflects improper prescribing and diversion of opioids, including J&J's products. J&J also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of its products to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

186. Also, J&J knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing of prescription opioids; and (iii) permitting and directing sales representatives to visit prescribers whose were engaging in suspicious conduct.

5. Par, Impax, and Amneal Knowingly Participated in Tennessee's Illegal Drug Market

187. Par, Impax, and Amneal, on their own and through their association with Endo, have knowingly participated in the illegal drug market.

188. Impax has oversupplied Tennessee and the Baby Doe Plaintiffs' community with generic Opana ER and shirked its diversion control obligations. As discussed above, when Opana ER was removed from the market in 2017 for safety reasons, Impax cynically viewed it as a business opportunity, entering into a profit-sharing agreement with Endo whereby Impax and Amneal became the only supplier of oxymorphone ER on the market while giving Endo a cut of the profits.

189. Impax first began developing its generic oxymorphone ER products when it knew that the branded Opana ER was undergoing a reformulation intended to address the rampant abuse

of the drug. Endo represented to the FDA and to Impax that the same formulation was being removed from the market for safety reasons. It was this admittedly dangerous and widely-abused drug that Impax put into the market.

190. In addition to knowing how widely abused its oxymorphone ER formulation was, Impax was also aware that the market it was entering following the removal reformulated Opana ER was, in essence, Opana ER addicts, the large majority of which resided in Tennessee.

191. In addition to its association with Impax and Endo, Amneal is also a generic opioid manufacturer and has shipped an extraordinary amount of prescription opioids into Tennessee, including oxycodone and hydrocodone. From 2006 to 2014, Amneal was the fourth-highest supplier of oxycodone and hydrocodone products in the state of Tennessee. Amneal knowingly filled suspicious orders (rather than halting them), shipped opioids illegally without diversion control, and otherwise knowingly failed to effectively prevent diversion, which led to the growth of the illegal opioid market Tennessee and the Baby Doe Plaintiffs' community.

192. Par also manufactures generic opioids, and since its acquisition by Endo International plc, has served as Endo's generic counterpart. Par has distributed billions of opioid pills throughout the country, including Tennessee and the Baby Doe Plaintiffs' community. Of these billions of pills shipped, Par reported less than 10 suspicious orders to the DEA from 2010 to 2019. From 2006 to 2014, Par was the third-highest supplier of oxycodone and hydrocodone products in the state of Tennessee.

193. Par, Impax, and Amneal knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Par, Impax, and Amneal are aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Par, Impax, and Amneal knew that such inflated prescribing necessarily reflects

improper prescribing and diversion of opioids, including their respective products. Nevertheless Par, Impax, and Amneal knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of its products to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

6. Teva Knowingly Participated in Tennessee's Illegal Drug Market

194. Teva continues to flood Tennessee with opioids in an amount that clearly contributes to the illegal opioid drug market.

195. Teva's generic oxycodone and hydrocodone products both represent the largest market share for either product throughout Tennessee according to IMS Health Data. These quantities of opioid pills clearly exceed the number that would be appropriate for normally prescribed therapeutic use and contribute to the illegal Tennessee opioid market.

196. Teva also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of its products to suspect physicians and pharmacies in Tennessee, without disclosing suspicious orders as required by applicable regulations.

197. According to IMS data, from September 2015 to August 2016, Teva accounted for 33.5% of the hydrocodone prescribed in Tennessee, 28.8% of the oxycodone prescribed in Tennessee, 16.8% of the oxymorphone, and 1.6% of the hydromorphone. This amounted to 1,913,712 Tennessee opioid prescriptions filled by Teva in one year. On average, this means Teva filled an opioid prescription for one out of every 3.5 Tennesseans during that year.

198. During the same timeframe of September 2016 through August 2017, Teva accounted for 32.3% of Tennessee hydrocodone prescriptions, 25.1% of its oxycodone prescriptions, 1.8% of its oxymorphone prescriptions, and 1.8% of its hydromorphone

prescriptions. This amounted to 1,619,143 Tennessee opioid prescriptions filled by Teva in one year. On average, this means Teva filled an opioid prescription for one out of every 4.1 Tennesseans during that year.

199. Teva's role relative to branded drugs involved knowing participation in the illegal drug market. Cephalon, a pharmaceutical company purchased by Teva in 2011, sold two opioid drugs, Actiq and Fendora. As part of the approval process for Actiq the FDA required a risk management program (RMP) for the marketing of the drug. The RMP for Actiq in 1998 specifically included special adverse event reporting for adverse events related to "unintended pediatric exposure," "diversion (i.e., use by an individual other than for whom it was prescribed)," or "in the context of 'off label use'". As of 2001, the FDA further informed Cephalon that it had concerns that its fentanyl-based drug, Actiq, might be used by patients who were not indicated for its use and that there was potential for diversion and abuse of the drug. In 2006 The Wall Street Journal reported that Actiq, a fast-acting lollipop like oral analgesic that contained fentanyl, was reportedly being called "perc-a-pop" on the street.[67]

200. In 2005, Cephalon knew that 90% of Actiq prescriptions were for off-label use, and 55% of that total were for chronic back pain. From 2000 to 2006, sales of Actiq grew from $15 million to over $400 million a year.[68] The Wall Street Journal further reported that surveys from research firm ImpactRx from June 2005-October 2006 found that more that 80% of patients who use the drug don't have cancer.[69]

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[67] John Carreyrou, *Narcotic 'Lollipop Becomes Big Seller Despite FDA Curbs*, Wall Street Journal, Nov. 3, 2006, available at: https://www.wsj.com/articles/SB116252463810112292.
[68] *Id.*
[69] *Id.*

201. In 2006, as Actiq was losing its patent protection as a branded drug, Cephalon began marking a new fentanyl-based drug to replace it, called Fentora. Fentora, like Actiq, was only ever approved by the FDA for the treatment of breakthrough cancer pain. As part of the FDA approval of Fentora, Cephalon again was required to agree to a risk management program or RiskMAP, including a plan to monitor, evaluate and determine the incidence of use of Fentora by opioid intolerant individuals, misuse of Fentora, and unintended (accidental) exposure to Fentora.

202. In November 2007, Cephalon submitted a supplemental New Drug Application (sNDA) to the FDA requesting that the FDA approve Fentora for use in non-cancer opioid tolerant patients with breakthrough pain. The FDA denied Cephalon's request, explaining that "[i]n the face of a national crisis of prescription opioid abuse and misuse, it is critical that you provide a risk management program with established efficacy [and] adequate restrictions to avoid widespread abuse and misuse."[70] The FDA's letter to Cephalon denying its request addressed the complete failure of the company to address the abuse and misuse of both its potential and its existing products:

> [Y]ou have not adequately addressed the public health concern of increased abuse, misuse, overdose and addiction that is to be expected with more widespread availability of this product in the community. Your proposed plan to mitigate these risks has not been adequately tested to assure that it will, indeed, achieve this outcome for your currently approved indication, let alone the proposed expanded indication.[71]

These problems were never resolved by Cephalon in an amended application and the FDA never approved Fentora for expanded use beyond cancer pain.

[70] Ex. 29 to Condodina Dep. (Sept. 12, 2008 letter from the FDA).
[71] *Id.*

203. Teva expanded its opioid business beyond Actiq and Fentora when it bought pharmaceutical company Actavis, which produces several generic opioids, mainly hydrocodone-acetaminophen and oxycodone-acetaminophen. Those types of opioids are prevalent in Tennessee.

204. After the FDA in 2012 required all opioid manufacturers to adopt a strategy to combat opioid abuse, Teva began developing a new branded opioid called Vantrela. In seeking FDA approval of the drug, Teva presented Vantrela as an "abuse-deterrent" form of hydrocodone. Teva then developed a marketing plan to target managed care organizations in the hopes they would add this new drug to their formulary. The opioids that Teva sold were the generic versions of these same opioids. In fact, Teva sold millions of those same opioids in Tennessee from, and as part of its pitch, Teva cited to publicly available documents that demonstrated that the U.S. was in the midst of an opioid abuse and addiction crisis.

205. In 2015 and 2016, Teva was reviewing and sharing publicly available information and studies about opioid addiction in preparation for Teva's third-party payer marketing strategy for Vantrela, planning to promote Vantrela as an abuse deterrent product. One such publicly available source was a Time Magazine article in June 2015, highlighting the public health crisis of opioid addiction, including specifically in Tennessee. The Time story highlighted, among other things, that patients often buy the pills on the black market after becoming addicted, and approximately 1/5 of Americans who take opioids are estimated by the National Institutes of Health to be in danger of turning to the black market for more pills.

206. In June 2016 Actavis prepared a managed care overview to be provided to payers outlining why the misuse, abuse and diversion of opioids is a major public health concern, including the fact that in 2010 1 in 20 Americans over 12 abused opioids, in 2011 1 in 3 ER visits were opioid related, and in 2014 there were 18,000 opioid overdose deaths, a 300% increase in

deaths from 1999. Teva recognized that between 9-28% of misusers of pain relievers get their drugs through a doctor's prescription. Teva also recognized the substantial economic burden of opioid abuse on healthcare, workplace, criminal justice, and societal costs. Teva even cited studies showing that approximately 27% of chronic pain patients prescribed opioids for non-cancer pain are likely to abuse the drugs. Teva positioned its branded Vantrela as a cost savings for managed care payers compared to its generic opioids because generic opioids have a "high rate of abuse and generate enormous costs," lead to high levels of addiction, are responsible for around 2/3 of overdose deaths, contribute to increased healthcare costs and other indirect costs.

207. Despite now having clear knowledge of the risks of abuse of opioids, including its own opioid products, Teva continued to send its generic opioid products into Tennessee and throughout the United States in large numbers. Vantrela was approved by the FDA in January 2017, yet Teva continues to promote its generic, less abuse-deterrent drugs.[72] From 2015-2017, IMS data shows that over 2 million Teva produced opioids prescriptions were filled in Tennessee.

208. Like the other Drug Producer Defendants, Teva received chargeback data from its distributors that told Teva precisely where its pills were going, in what amount, and to whom. It had the ability to deny chargebacks relative to pharmacies and dispensing physicians supplied by its distributors, which effectively amounted to controlling whether its pills would reach those pharmacies or not. And like other defendants, it recognized when orders were manifestly suspicious (because of the size of the order, the size of the community served, and other indicators) and likely to be diverted. However, it rarely, if ever, denied chargebacks relative to pharmacies anywhere in the country, let alone in Tennessee. Instead, it chose to fill those suspicious orders

[72] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207975Orig1s000Approv.pdf

anyway, including in Tennessee, recognizing that the shipments were likely being dispensed to fill pill mill prescriptions or otherwise to be diverted into the black market.

209. Teva recognized that prescription rates per capita are an indicator of potential abuse of prescription opioids. Nevertheless, Teva continued to fill orders in the Baby Doe Plaintiffs' community where the per capita prescription rates were high and that Teva knew or should have known had no legitimate medical need for the opioids being sold there. Instead of recognizing these orders as suspicious and reporting them to the DEA, Teva simply continued on with business as usual in filling millions of prescriptions for its generic opioids that Teva knew were being widely abused and misused.

210. As with the other defendants, Teva's suspicious order monitoring system did not actually detect suspicious orders. Upon information and belief, Teva placed primary responsibility for detecting and reporting suspicious orders with its sales personnel, who were financially incentivized to call on customers who made suspicious prescriptions or submitted suspicious orders rather than report them, and to come up with sham justifications to "clear" suspicious orders or to justify calling on them further. From 2002 to 2011, Teva did not report a single one of its prescription orders as suspicious. In fact, prior to being named in numerous opioid-related lawsuits, Teva's SOM system has only flagged – and Teva only reported to the DEA – 6 TOTAL suspicious orders for the entire country. The included just one in 2013, one in 2014, four in 2015, and none in 2016. Otherwise, Teva supplied essentially anyone and everyone who submitted an order for its drugs. This included filling orders that it recognized were being dispensed, in large volumes, to fill prescriptions relative to prescribers under circumstances that Teva recognized were suspicious and indicative of diversion.

211. Teva shipped orders of opioids in frequencies and in volumes that were inherently suspicious. For example, in April 2015 alone, Teva shipped nearly 5 million pills of hydrocodone into Tennessee, through AmerisourceBergen, McKesson, and others. The multitude of orders comprising this volume necessarily were suspicious. Yet Teva filled them. Upon information and belief, Teva filled similarly large volumes of orders from all of the Distributor Defendants for pharmacies and dispensing physicians within Tennessee, under circumstances demonstrating that each order was suspicious.

212. Other than its so-called suspicious order monitoring program, Teva does nothing to prevent the illegal diversion of its prescription opioid products once the products leave the individual manufacturing facilities, even though it knew that some customers of prescription opioids obtain them expressly for nonmedical purposes. Teva is also aware that the opioid drug diversion problem is particularly large and problematic in Tennessee.

213. As with the other Defendants:

a. Teva's suspicious order monitoring program was structured to be ineffective.

b. Teva, like the other Producer Defendants, utilized a sales force to sell its branded opioids who called on prescribers directly and on pharmacies and dispensing physicians – nationwide and in Tennessee.

c. Teva, like the other Producer Defendants, paid sales representatives of its branded opioids bonuses or commissions based on sales volume relative to Tennessee (as elsewhere).

d. Relative to branded sales, Teva financially incentivized its sales force to call on high-volume prescribers and targeted those high-volume prescribers to prescribe more opioids.

e. Relative to its relationship with pharmacies and dispensing physicians, Teva financially incentivized its sales personnel to process and fill suspicious orders.

214. Teva knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Teva is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Teva knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Teva's products. Teva also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of its products to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein. This included knowingly and illegally distribution opioids without effective controls against diversion and filling suspicious orders.

215. Also, Teva knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing of prescription opioids; and (iii) permitting and directing sales representatives to visit prescribers whose were engaging in suspicious conduct.

C. The Distributor Defendants Participated in the Illegal Drug Market

1. The Distributor Defendants' Business Models are Unlawful or Otherwise Facilitated Diversion

216. The Distributor Defendants facilitated illegal drug transactions in Tennessee by submitting suspicious orders, having them filled, and stocking suspect pharmacies and dispensing physicians with opioids destined for the illegal drug market. They had a choice when faced with suspicious orders: submit them or impound them and investigate until they actually cleared the suspicion. They consistently chose to ship opioids to downstream buyers who were likely – and in

many instances were criminally convicted for – diverting prescription opioids. They also acted by promoting their services to suspect pharmacies and dispensing physicians to drive sales volumes, knowing that doing so would encourage diversion. Furthermore, to avoid reporting their own customers, they provided sham justifications for suspicious orders to the Producer Defendants, as part of a "nod, nod, wink, wink" collaboration between the Distributor Defendants and the Producer Defendants. Essentially, the Distributor Defendants recognized that the Producer Defendants would accept essentially any purported justification for an inherently suspicious order. Through this "nod nod, wink wink" arrangement, the Distributor Defendants and Drug Producers collaborated to put prescription drugs into the illegal market without alerting law enforcement or losing their best customers.

217. Through these depraved acts and schemes, the Producer Defendants and the Distributor Defendants helped each other get rich from the devastation that they wrought on Tennessee communities, including the Baby Doe Plaintiffs' community. This included causing increasing numbers of opioid overdose abuse deaths each year – including 1,543 deaths in 2019 and 2,388 deaths in 2020 – and staggering rates of NAS births, including over 1,600 babies born with NAS in Tennessee over the last two years. The Producer Defendants and Distributor Defendants did not care about the human and economic toll on Tennesseans that their misconduct caused – all they cared about was profit.

218. ABC, Cardinal, H.D. Smith, McKesson, and M&D account for about 95% of the market nationwide, and an equivalent amount in Tennessee. Drugs distributed by these companies therefore comprise the vast majority of drugs that reached the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. The Distributors essentially acted as the suppliers for the illegal drug market.

219. The Drug Distributor Defendants know that they have an important responsibility to monitor their customers' practices and that they are not supposed to fill suspicious orders.

220. The Distributor Defendants knew they should monitor, detect, and halt suspicious orders. For example, industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[73] The guidelines set forth recommended steps in the "due diligence" process, and note in particular "[i]f an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[74]

221. The Distributor Defendants sold prescription opioids in and around the Baby Doe Plaintiffs' community, which Defendants knew were likely to be diverted into the illegal drug market.

222. DEA Agent Joseph Rannazzisi has emphasized the importance of the Distributor Defendants in preventing opioid diversion: "[b]ecause distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances . . . from legitimate channels into the illicit market, it is

[73] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061, Doc. No. 1362415 (App'x B) (D.C. Cir. Mar. 7, 2012).
[74] *Id.*

incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the [Controlled Substances Act] collapses."[75]

223. The sheer volume of prescription opioids distributed to pharmacies in the Baby Doe Plaintiffs' community is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

224. The Distributor Defendants filled inherently suspicious orders originating from the Baby Doe Plaintiffs' community which the Distributor Defendants knew were likely to be diverted to or within the Baby Doe Plaintiffs' community.

225. The Distributor Defendants filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, orders of unusual frequency in the Baby Doe Plaintiffs' community, and orders which Defendants knew or should have known were likely to be diverted into the Baby Doe Plaintiffs' community.

226. Distributor Defendants possessed direct knowledge of obvious signs of diversion by their customers. They knew that Tennessee pharmacies were receiving prescription opioids in volumes grossly disproportionate to the population and any conceivable medical need. They knew that local prescribers near those pharmacies were prescribing at levels that were not medically justifiable and that the pharmacies were filling prescriptions for suspect prescribers.

227. Rather than seek to stop pharmacies from supplying pills or to stop dispensing physicians who were operating pill mills, the Distributor Defendants targeted these entities and

[75] Declaration of Joseph Rannazzisi, ¶ 10 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (D.D.C. February 10, 2012).

competed for their business. In other words, the Distributor Defendants targeted high-volume dispensing pharmacies (including independent or locally owned pharmacies) to compete for their business. Effectively, they competed for pill mill market share.

228. The Distributor Defendants have been subject to repeated investigations and citations for streaming prescription opioids into the illegal drug market.

229. For example, on September 27, 2006, the DEA sent a letter to "every commercial entity in the United States registered with the [DEA] to distribute controlled substances."[76] The letter stated that manufacturers and distributors "share responsibility for maintaining appropriate safeguards against diversion" and "given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, ***even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm***."[77] The letter advised that "DEA will use its authority to revoke and suspend registrations in appropriate cases."[78] The letter also provides that "in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[79] The letter further discusses that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[80]

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[76] 2006 Rannazzisi Letter at 1.
[77] *Id.* at 2 (emphasis added).
[78] *Id.*
[79] *Id.*
[80] *Id.* at 1.

230. The DEA sent another letter on December 27, 2007 to "reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders." [81] This letter reminded manufacturers and distributors of their obligation to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[82]

231. The letter states that in terms of reporting suspicious orders:

> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."[83]

The 2007 letter also said that "[f]ailure to maintain effective controls against diversion is inconsistent with the public interest . . . and may result in the revocation of the registrant's DEA Certificate of Registration."[84]

232. The 2007 letter also references the final order issued in Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007), which "[i]n addition to discussing the obligation to

[81] 2007 Rannazzisi Letter at 1.
[82] *Id.*
[83] *Id.* at 2.
[84] *Id.* at 1-2.

report suspicious orders when discovered" and "some criteria to use when determining whether an order is suspicious," the order "also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances."[85]

233. The Distributor Defendants knew which pharmacies and dispensing physicians were filling prescriptions, including the amount and type of drug. The Distributor Defendants maintained direct relationships with pharmacies and dispensing physicians, including those plainly engaging in filling pill mill prescriptions *en masse*.

234. The illegal market for prescription opioids exists because distributors choose to submit suspicious orders to manufacturers, manufacturers choose to fill them, and the distributors distribute them to suspect pharmacies where they fill prescriptions written by pill mill doctors. In American Overdose, Mr. Rannazzisi summed up the role of distributors: To Rannazzisi, distributing highly addictive and potentially lethal drugs wasn't the same as delivering chocolate bars. He regarded the lucrative licenses the wholesalers held—McKesson is the fifth-biggest company on the Fortune 500 index with around $200 billion in revenue—as carrying particular responsibilities: "These companies have one task, and that is the safe and secure distribution of drugs, particularly prescription drugs. Otherwise FedEx or UPS could do this role. This isn't a compliance challenge, like gender discrimination at a tech company, which is horrific, but it's not fundamental to their operation. This is the equivalent of a tech company failing on cybersecurity. If these companies were doing their job right, you shouldn't be seeing black-market prescription painkillers."

2. AmerisourceBergen Has a History of Facilitating Illegal Drug Transactions

[85] *Id.* at 2.

235. On April 24, 2007, the DEA issued an immediate suspension order ("ISO") on AmerisourceBergen's Orlando, Florida distribution center, alleging that AmerisourceBergen was not controlling shipments of prescription opioids to Internet pharmacies and revoking the facility's license to distribute controlled substances.[86]

236. On June 22, 2007, AmerisourceBergen entered into a settlement with the DEA which led to the reinstatement of the Orlando distribution center's suspended license.[87] Under that agreement, AmerisourceBergen was required to implement an enhanced order-monitoring program in all of its distribution centers by June 30, 2007.[88]

237. In 2012, West Virginia's then-Attorney General Darrell McGraw filed lawsuits against AmerisourceBergen, Cardinal Health, and a dozen smaller drug distributors for their role in a drug supply chain that includes doctors who write prescriptions for nonmedical purposes and "pill mill" pharmacies that dispense excessive numbers of painkillers, including opioids.[89] In February 2017, Cardinal Health and AmerisourceBergen agreed to pay $20 million and $16 million, respectively, to resolve West Virginia's claims.[90]

238. The settlement, which is believed to be the largest pharmaceutical settlement in West Virginia history, came shortly after a Charleston Gazette-Mail investigation revealed that drug wholesalers shipped 780 million hydrocodone and oxycodone pills to West Virginia in just six years – a period when 1,728 West Virginians fatally overdosed on those two drugs.[91]

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[86] 2007 AmerisourceBergen Corporation Form-10K. Available at: https://www.sec.gov/Archives/edgar/data/1140859/000119312507255013/d10k.htm.
[87] *Id.*
[88] *Id.*
[89] Eric Eyre, 2 drug distributors to pay $36M to settle WV painkiller lawsuits, Charleston Gazette-Mail, January 9, 2017. Available at: http://www.wvgazettemail.com/news-cops-and-courts/20170109/2-drug-distributors-to-pay-36m-to-settle-wv-painkiller-lawsuits.
[90] *Id.*
[91] *Id.*

AmerisourceBergen alone shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills from 2007 to 2012. McKesson shipped 3.3 million hydrocodone pills to a single county.[92] And Cardinal Health and AmerisourceBergen combined to ship nearly 40 percent of all hydrocodone and oxycodone pills to West Virginia.[93]

239. According to unsealed court documents from the West Virginia case, AmerisourceBergen distributed 149,300 hydrocodone pills – or 12,400 pills a month – to Tug Valley Pharmacy in Mingo County in 2009.[94] The pharmacy filled prescriptions for Drs. Diane Shafer, Katherine Hoover and William Rykman, who operated "sham" pain clinics in Williamson.[95] Federal agents raided the clinics in 2010 and they never reopened.[96]

240. Unsealed court documents from that case further evidence that AmerisourceBergen shipped 8,000 hydrocodone painkiller tablets to a drive-thru pharmacy over two days in July 2012.[97] On those same two days, a competing drug wholesaler shipped 8,600 hydrocodone tablets to the same "pill mill" pharmacy.[98] AmerisourceBergen sold another 3,800 oxycodone pills to the same pharmacy that month.[99]

241. AmerisourceBergen also sent 16 billion pills to Missouri in a five-year period, during which time it reported only ***244 suspicious orders nationwide***.[100]

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[92] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html
[93] *Id.*
[94] Eric Eyre, *18 'words' reveal drug giant's pain pill shipments to WV*, Charleston Gazette-Mail, May 25, 2016. Available at: http://www.wvgazettemail.com/news/20160525/18-words-reveal-drug-giants-pain-pill-shipments-to-wv.
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] https://www.npr.org/sections/health-shots/2018/07/12[redacted]report-1-6-billion-opioid-doses-poured-into-missouri-over-6-years.

242. In 2017, AmerisourceBergen plead guilty to illegally distributing misbranded drugs and agreed to pay $260 million to resolve criminal liability for its distribution of drugs from a facility that was not registered with the FDA.

243. In 2018, AmerisourceBergen entered into a Corporate Integrity Agreement ("CIA") with the U.S. Dept. of Health & Human Services, and agreed to pay $625 million to resolve civil fraud charges.

244. Upon information and belief, AmerisourceBergen had a sales force responsible for establishing relationships with pharmacies and dispensing physicians. Upon information and belief, AmerisourceBergen premised utilized sales of prescription opioids as a basis for sales representative compensation at least through 2012. Upon information and belief, AmerisourceBergen continued to compensate sales personnel at least in part based on volume, providing a financial incentive to fill suspicious orders and not to report dispensers that engaged in diversion and supplied pill mills.

245. AmerisourceBergen has engaged in the same misconduct relative to Tennessee that it did in the preceding paragraphs. This involved repeatedly filling suspicious orders without due diligence, and otherwise shipping excessive amounts of opioids to pharmacies and dispensing physicians in Tennessee at levels far exceeding any conceivable legitimate need.

246. AmerisourceBergen recognized that many of its customers in Tennessee were supplying the illegal drug market, filling prescriptions for pill mills, and otherwise filling prescriptions far beyond any legitimate medical need. AmerisourceBergen observed firsthand obvious signs of diversion by its customers, including parking lots filled with out-of-state license plates and reports from law enforcement concerning the involvement of pharmacies in supplying criminals with opioids, but chose to keep supplying those accounts anyway. It also filled orders

originating in Tennessee and Baby Doe Plaintiffs' community of unusual size or frequency, or that the Distributor Defendants otherwise recognized were indicative of diversion.

247. AmerisourceBergen knowingly shipped orders to fill prescriptions issued by pill mill operators and other over-prescribers in Tennessee and Baby Doe Plaintiffs' community, including but not limited to the Prescriber Defendants in this action and the other prescribers referenced herein.

248. AmerisourceBergen knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. AmerisourceBergen is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. AmerisourceBergen knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids. AmerisourceBergen also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of opioids to physicians and pharmacies whose prescribing/dispensing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

249. Also, AmerisourceBergen knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing/dispensing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for clearing suspicious orders for prescription opioids; and (iii) permitting and directing SOM personnel to prioritize clearing orders over reporting them.

3. Cardinal Health Has a History of Facilitating Illegal Drug Transactions

250. On September 27, 2006, the DEA sent a letter to Cardinal reminding Cardinal that it was the distributors' responsibility to ensure that their products were not diverted for illicit use. The letter reminded Cardinal that it could not "simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances." Cardinal and, upon information and belief, all the other defendants in this action nevertheless used that an entity was registered as a basis to submit and fill plainly suspicious orders.

251. Based on findings from DEA investigations, in November and December 2007, the DEA issued three Immediate Suspension Orders ("ISOs") to Cardinal Health.

252. On November 28, 2007, the DEA issued an ISO to Cardinal Health in connection with its distribution center in Auburn, Washington (the "Auburn Facility"), immediately suspending the facility's Certificate of Registration because its continued registration constituted "an imminent danger to public health and safety."[101]

253. According to the ISO, the Auburn Facility repeatedly "distributed unusually large amounts of hydrocodone" to Horen's Drugstore, Inc. ("Horen's Drugstore") – distributing 600,000 dosage units of hydrocodone to Horen's Drugstore from March 2007 through September 2007 – and "disregard[ed] the clear indications that Horen's Drugstore was engaged in the diversion of controlled substances[.]" Horen's Drugstore was Cardinal Health's largest purchaser of combination hydrocodone products in 2007, and according to the ISO, the drugstore was "a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone

[101] *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-15 ("Settlement and Release Agreement and Administrative Memorandum of Agreement"), ¶ 2, Appendix B (D.D.C. 2012). (Hereinafter "2008 Cardinal Health MOA").

based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law." The DEA found that Cardinal Health "failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels," and concluded that its continued registration with the DEA constituted "an imminent danger to the public health and safety."

254. On December 5, 2007, the DEA issued an ISO notifying Cardinal Health of the immediate suspension of its Lakeland, Florida drug distribution facility for failure to maintain effective controls against diversion of hydrocodone.[102]

255. The ISO detailed how, from August 2005 through October 2007, Cardinal Health failed to maintain effective controls against the diversion of hydrocodone into other than legitimate medical, scientific and industrial channels. According to the ISO, Cardinal Health distributed hydrocodone to various pharmacies, even though the company knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as defined in the CSA. For example, Cardinal Health distributed 1,213,000 dosage units of hydrocodone to Q-R-G, Inc. over the course of February to June 2006, and approximately 1,148,100 dosage units to United Prescription Services, Inc. from July to October 2006. The ISO further detailed that, on September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for Cardinal Health, sent an email to the DEA stating that Cardinal Health discontinued all sales of controlled substances to 13 Internet pharmacies, including RKR Holdings, Inc. Nevertheless, from September 1, 2006 to January 31, 2007, Cardinal Health distributed 393,600 dosage units of hydrocodone products to RKR Holdings. As explained therein Cardinal distributed over 8,000,000 dosage units of hydrocodone products to customers that it knew or should have known

[102] *Id.* at ¶ 3, App'x C.

were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels.[103] Indeed, the ISO indicated that many of Cardinal's largest purchasers "were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice."

256. On December 7, 2007, the DEA issued an ISO to Cardinal Health regarding its distribution center in Swedesboro, New Jersey which, from January 2005 to August 2007, "distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels."[104]

257. The ISO stated that some of Cardinal Health's "largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice."

258. In addition to the November and December 2007 ISOs, on January 30, 2008, the DEA issued an Order to Show Cause as to why the agency should not revoke the Certificate of Registration assigned to Cardinal Health's Stafford, Texas distribution center for the improper distribution of hydrocodone.[105] The DEA also found that Cardinal Health failed to maintain effective controls against the diversion of controlled substances at its McDonough, Georgia facility, Valencia, California facility, and Denver, Colorado facility. In total, the DEA had reason

[103] *Id.* at ¶ 2.
[104] *Id.* at ¶ 4, App'x D.
[105] *Id.* at ¶ 5, App'x E.

to believe that seven of Cardinal Health's twenty-seven then-registered distribution centers were not adhering to their obligations under the CSA.

259. On December 27, 2007, the DEA sent another letter to Cardinal reminding it that all distributors had an obligation to maintain effective controls against diversion.[106]

260. Following the three 2007 ISOs and the Order to Show Cause, the DEA and Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("MOA") on September 29, 2008.[107] Pursuant to the MOA, Cardinal Health agreed to pay a civil fine of $34 million, and "maintain a compliance program designed to protect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations."[108]

261. After entry of the 2008 MOA, Cardinal Health began violating the CSA again almost immediately. A further investigation of Cardinal Health's Lakeland, Florida facility by the DEA "revealed a persistent failure to exercise due diligence to ensure that controlled substances were not being diverted" over a period of approximately 3 years, from November 2008 to December 2011.[109] The lack of anti-diversion controls resulted in the top four customers of Cardinal Health's Lakeland facility being supplied with approximately 50 times the amount of oxycodone compared to the average Florida retailer that Cardinal Health services, which the DEA referred to as a "staggering" difference in distribution.[110] Of those four pharmacies, one was found

[106] *Cardinal Health, Inc. v. Holder*, Decl. of J. Rannazzisi, doc no. 14-2 at 12.
[107] *Id.*
[108] *Id.*
[109] *Id.* at ¶ 75.
[110] *Id.* at ¶ 76.

to be "dispensing oxycodone 30mg prescriptions . . . for persons whose addresses were in Kentucky and Tennessee and who paid cash."[111]

262. The DEA's further investigation culminated in the issuance of another ISO regarding the Lakeland, Florida facility on February 2, 2012 (the "2012 ISO") for failure to maintain effective controls against diversion of oxycodone.[112]

263. The 2012 ISO stated that, "[d]espite the MOA, the specific guidance to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA]."[113] According to the ISO:

> From January 1, 2008 through December 31, 2011 . . . Cardinal's sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units. . . . From 2008 to 2009, Cardinal's sales to its top four retail pharmacy customers increased approximately 803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacy customers increased approximately 162%. [¶] The egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal's Florida retail pharmacies, which receive, on average, approximately 5,347 dosage units of oxycodone per month.[114]

264. The 2012 ISO further provided that "[n]otwithstanding the large quantities of controlled substances ordered by Cardinal's top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into

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[111] Holidays CVS, LLC d/b/a CVS Pharmacy Nos. 219 and 5195 Decision and Order, 77 Fed. Reg. 62316, 62318 (Oct. 12, 2012).
[112] *Cardinal Health, Inc. v. Holder*, Case No. 1:12-cv-00185, Dkt. 14-18 (D.D.C. 2012).
[113] *Id.* at ¶ 3.
[114] *Id.* at ¶ 4.

other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers."[115]

265. In May 2012, following a DEA investigation, Cardinal Health entered into a second memorandum of agreement relative to its 28 registered distribution facilities. The MOA required Cardinal to maintain a compliance program to monitor and detect diversion, to implement a system for conducting an in-person investigation for any suspicious orders."

266. On December 23, 2016, Cardinal Health agreed to pay a $34 million fine (separate from the $34 million fine in 2008) to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.[116]

267. Also on December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to "timely identify suspicious orders of controlled substances and inform the DEA of those orders" or to "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."

268. Upon information and belief, Cardinal Health had a sales force responsible for establishing relationships with pharmacies and dispensing physicians. Upon information and belief, Cardinal Health utilized sales of prescription opioids as a basis for sales representative

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[115] *Id.* at ¶ 5.

[116] Press Release, United States Reaches $34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act, DOJ, U.S. Attorney's Office – Middle District of Florida. Available at: https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under.

compensation at least through 2012. Upon information and belief, Cardinal Health continued to compensate sales personnel at least in part based on volume, providing a financial incentive to fill suspicious orders and not to report dispensers that engaged in diversion and supplied pill mills.

269. Cardinal Health has engaged in the same misconduct relative to Tennessee that it did in the preceding paragraphs. This involved repeatedly filling suspicious orders without due diligence, and otherwise shipping excessive amounts of opioids to pharmacies and dispensing physicians in Tennessee at levels far exceeding any conceivable legitimate need.

270. Cardinal Health recognized that many of its customers in Tennessee were supplying the illegal drug market, filling prescriptions for pill mills, and otherwise filling prescriptions far beyond and legitimate medical need. Cardinal Health observed firsthand obvious signs of diversion by its customers, including parking lots filled with out of state license plates and reports from law enforcement concerning the involvement of pharmacies in supplying criminals with opioids, but chose to keep supplying those accounts anyway. It also filed orders originating in Tennessee and Plaintiffs' community of unusual size or frequency, or that Cardinal Health otherwise recognized was indicative of diversion.

271. Upon information and belief, Cardinal Health knowingly shipped orders to fill prescriptions issued by pill mill operators and other over-prescribers in Tennessee and Plaintiffs' community, including but not limited to the Prescriber Defendants in this action and the other prescribers referenced herein.

272. Cardinal knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Cardinal is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Cardinal knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids. Cardinal

also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of opioids to physicians and pharmacies whose prescribing/dispensing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

273. Also, Cardinal knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing/dispensing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for clearing suspicious orders for prescription opioids; and (iii) permitting and directing SOM personnel to prioritize clearing orders over reporting them.

4. McKesson Has a History of Facilitating Illegal Drug Transactions

274. On May 2, 2008, McKesson agreed to pay a total of $13.25 million in civil penalties to six U.S. Attorney's Offices to settle allegations that the company violated federal reporting provisions relating to its handling of prescription painkillers, including hydrocodone.[117]

275. In a press release regarding the agreement, the Department of Justice explained:

> Three McKesson distribution centers received and filled hundreds of suspicious orders placed by pharmacies participating in illicit Internet schemes, but failed to report the orders to DEA. They did so even after a Sept. 1, 2005, meeting at which DEA officials met with and warned McKesson officials about excessive sales of their products to pharmacies filling illegal online prescriptions. The pharmacies filled purported online "prescriptions" for hydrocodone (contained in drugs such as Vicodin), but the prescriptions were issued outside the normal course of professional practice and not for a legitimate medical purpose. The United States Attorneys allege that the orders that McKesson received from these pharmacies were unusually large, unusually frequent, and/or deviated substantially from the

[117] Press Release, McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications, Dept. of Justice, May 2, 2008. Available at: https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html.

> normal pattern. As a result, millions of dosage units of controlled substances were diverted from legitimate channels of distribution.[118]

276. As part of the 2008 agreement, McKesson was required to "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders . . . and follow procedures established by [McKesson's] Controlled Substance Monitoring Program ("CSMP")." McKesson flagrantly violated those provisions of the agreement.[119]

277. A federal government investigation revealed that, from 2008 to 2013, McKesson did not fully implement its compliance program, and, instead, supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills.[120] For example, in Colorado, McKesson processed more than 1.6 million orders for controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious.[121] This included filling every order by a pharmacist who was selling up to 2,000 pills per day in a suburban community of 38,000 people.[122] It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records, and bypassed suspicious order reporting procedures.

278. When confronted with the evidence gathered in the government's investigation, McKesson conceded that, following the 2008 agreement, the company:

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[118] *Id.*

[119] 2017 Administrative Memorandum of Agreement (DOJ, DEA and McKesson). Available at: https://www.justice.gov/opa/press-release/file/928476/download. (Hereinafter "2017 McKesson MOA").

[120] Press Release, *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, Dept. of Justice, January 17, 2017. Available at: https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[121] *Id.*

[122] https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?noredirect=on&utm_term=.827ab6d7a014

- "[F]ailed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA . . . at the McKesson Distribution Centers" located in: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs California; Washington Courthouse, Ohio; and West Sacramento, California;[123]

- "[F]ailed to properly monitor its sales of all controlled substances and report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements";[124]

- "[F]ailed to conduct due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious reporting procedures set forth in the McKesson CSMP";[125]

- "[F]ailed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency";[126]

- "[F]ailed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters";[127] and

- "[D]istributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners in the usual course of their professional practice."[128]

279. Following the federal government's investigation, in January 2017, McKesson entered into an Administrative Memorandum of Agreement with the DEA wherein it agreed to

[123] 2017 McKesson MOA at 3.
[124] *Id.* at 4
[125] *Id.*
[126] *Id.*
[127] *Id.*
[128] *Id.*

pay a $150,000,000 civil penalty for violation of the 2008 agreement as well as failure to identify and report suspicious orders of controlled substances at its drug distribution centers across the country.[129] One of McKesson's largest sources of opioids, Mallinckrodt, admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson further admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distributions Centers" including the McKesson Distribution Center located in Washington County, Ohio. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities. The 2017 agreement further required McKesson to suspend sales of controlled substances from its distribution centers in Colorado, Ohio, Michigan and Florida for multiple years.[130] The suspensions are among the most severe sanctions ever agreed to by a DEA registered distributor.

280. As explained in the *Washington Post* and on *60 Minutes*, the DEA investigation had demonstrated that McKesson had taken acts to support criminal diversion.[131] For example, the DEA found evidence that McKesson had shipped suspicious orders of millions of painkillers to

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[129] *Id.* at 8.
[130] *Id.* at 5-7.
[131] Lenny Bernstein & Scott Higham, *'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a wimper*, Washington Post, Dec. 17, 2017, https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html

pharmacies across the country that supplied drug rings. A DEA memo outlined its investigative findings concluded that McKesson "[i]gnored blatant diversion," had a "pattern of raising thresholds arbitrarily," "[f]ailed to review orders for suspicious activity," "[i]gnored its own procedures designed to prevent diversion," and "[s]upplied controlled substances in support of criminal diversion."[132]

281. On December 17, 2017, Assistant Special Agent David Schiller spoke on *60 Minutes*:

> If they woulda stayed compliance with authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near. . . . They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.[133]

282. Moreover, the DEA found evidence that McKesson raised distribution thresholds to high-volume pharmacies purposely to get around its suspicious order reporting obligations. When a pharmacy began to exceed its threshold, it would just raise the threshold again.[134] According to DEA officials, McKesson "paid little or no attention to the unusually large and frequent orders placed by pharmacies, ***some of them knowingly supplying drug rings***."[135] Instead, "the company raised its own self-imposed limits, known as thresholds, orders from pharmacies and ***continued to ship increasing amounts of drugs in the face of numerous red flags***."

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[132] *Id.*

[133] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Distributor*, 60 Minutes, Dec. 17, 2017, https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.

[134] *Id.*

[135] Lenny Bernstein & Scott Higham, *'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a wimper*, Washington Post, Dec. 17, 2017, https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html

283. McKesson had a sales force responsible for establishing relationships with pharmacies and dispensing physicians. McKesson utilized sales of prescription opioids as a basis for sales representative compensation at least through 2012. McKesson continued to compensate sales personnel at least in part based on volume, providing a financial incentive to fill suspicious orders and not to report dispensers that engaged in diversion and supplied pill mills.

284. McKesson engaged in the same misconduct relative to Tennessee pharmacies and pharmacies supplying the illegal drug market in Baby Doe Plaintiffs' community, including knowingly shipping orders from pharmacies and dispensing physicians that were suspicious or likely to result in diversion (such as unusually large and frequent orders or orders that were unjustifiable relative to the local population served), arbitrarily raising distribution thresholds to avoid reporting the orders as suspicious, shipping increasing amounts of opioids in the face of numerous red flags, and otherwise supplying opioids in support of criminal diversion.

285. McKesson knowingly shipped orders to fill prescriptions issued by pill mill operators and other over-prescribers in Tennessee and Baby Doe Plaintiffs' community, including but not limited to the Prescriber Defendants in this action and the other prescribers referenced herein.

286. McKesson knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. McKesson is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. McKesson knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids. McKesson also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of opioids to physicians and pharmacies whose

prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

287. Also, McKesson knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing/dispensing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for clearing suspicious orders for prescription opioids; and (iii) permitting and directing SOM personnel to prioritize clearing orders over reporting them.

D. The Pharmacy Chain Defendants' Self-Distribution of Opioids Facilitated the Illegal Opioid Market in Tennessee

288. The Pharmacy Chain Defendants, in addition to purchasing opioid medications from the Distributor Defendants, also self-distributed opioid medications to their pharmacy locations.

289. The Pharmacy Chain Defendants had the same obligations under Tennessee law to monitor, detect, and halt suspicious orders as the Distributor Defendants. Similarly, the Pharmacy Chain Defendants repeatedly failed to identify, investigate, report, and/or halt hundreds of thousands of suspicious opioid orders across the country, including orders going to Tennessee.

290. The numbers that each Pharmacy Chain Defendant distributed into the State of Tennessee were staggering. From just 2006 to 2014:

a. Walgreens distributed 642,704,930 dosage units of opioids into Tennessee;

b. CVS distributed 186,897,900 dosage units into Tennessee;

c. Rite Aid distributed 82,412,650 dosage units into Tennessee; and

d. Walmart distributed 251,048,435 dosage units into Tennessee.

291. The Pharmacy Chain Defendants did not implement effective diversion control measures when shipping these pills. Instead, they put in place policies and protocols that ensured that the flow of drugs into the illegal market would continue.

1. CVS Knowingly Fueled the Illegal Opioid Market

292. Before 2009, CVS had no suspicious order monitoring system at all. Instead, it relied on individual "Pickers and Packers" to identify orders of unusual size, frequency, or pattern without clear criteria. CVS had not written policies, procedures, or protocols for the Pickers and Packers, no formal qualifications for the position, and no training.

293. In 2009, CVS at least began using a computer algorithm to flag suspicious orders, but that algorithm was flawed from the outset. The SOM did not function properly because it monitored by drug rather than active ingredient, such that changes in a drug's description or name caused the historical data (necessary for valid calculations) to be lost. The system also failed to account for orders made by and shipped to CVS pharmacies from third parties. Thus, as CVS itself admitted, a particular store could defeat the computer threshold simply by purchasing excess of the threshold from someone other than CVS. CVS knew that this resulted in filling suspicious orders from its pharmacies. At least as of July 2013, CVS internally had identified that CVS's supposed SOM process was irrelevant and pointless. CVS did not implement a SOM system until mid to late 2014, at which point its distribution centers stopped distributing Schedule II opioids at the whole level.

294. CVS did not conduct appropriate due diligence on flagged orders. It did not conduct meaningful diligence on more than a small fraction of flagged orders. In 2012 and 2013, CVS at times had only one employee reviewing all potentially suspicious orders for every CVS pharmacy in the country. CVS designed this program to fail, knowing that it would allow for suspicious

orders to be filled unabated. Upon information and belief, CVS never reported a single suspicious order to the Tennessee Board of Pharmacy.

295. CVS knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. CVS is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. CVS knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids. CVS also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of opioids to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

296. Also, CVS knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing/dispensing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for clearing suspicious orders for prescription opioids; and (iii) permitting and directing SOM personnel to prioritize clearing orders over reporting them.

2. Rite Aid Knowingly Fueled the Illegal Opioid Market

297. Rite Aid, as part of a multi-jurisdictional investigation by the DOJ was fined $5 million in penalties for violating the federal Controlled Substances Act ("CSA"). The investigation showed that from 2004 forward, Rite Aid pharmacies across the country knowingly filled prescriptions for controlled substances that were not issued for a medically legitimate purpose, failed to notify the DEA in a timely manner about thefts and losses of controlled substances, and/or failed to maintain or to furnish to the DEA upon request records that the CSA required to be kept in the ordinary course of business. Rite Aid also agreed to enter into a

compliance plan with the DEA to ensure that it implemented an effective monitoring program to prevent diversion. The investigation showed that Rite Aid's conduct had led to the diversion of opioids in communities across the country.

298. Despite these agreements, Rite Aid never identified or reported a suspicious order.[136] Moreover, even when Rite Aid was aware that a location's pharmacist-in-charge was filling prescriptions for illegitimate purposes, Rite Aid would not report that store's orders as suspicious.[137]

299. Rite Aid knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Rite Aid is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Rite Aid knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids. Rite Aid also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of opioids to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

300. Also, Rite Aid knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing/dispensing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for clearing suspicious orders for prescription opioids; and (iii) permitting and directing SOM personnel to prioritize clearing orders over reporting them.

3. Walgreens Knowingly Fueled the Illegal Opioid Market

[136] Rite Aid 30(b)(6) 27:17-19, 102:1-6, 263:18-22.
[137] Rite Aid 30(b)(6) 212:18-20.

301. Nationally, from 2006 to 2012, according to a Washington Post analysis, "Walgreens dominated the nation's retail opioids market."[138] During that period, Walgreens acted as its own wholesaler, obtaining 97 percent of pain pills directly from drug manufacturers, which allowed it to have more control over how many pain pills it sent to its stores.[139] Edward Bratton, Walgreens' manager of pharmaceutical integrity, described the company's SOM system prior to 2013 as a "system [that] would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone[.]"[140]

302. For example, Walgreens used rigid formulas to "detect" suspicious orders. The formulas simply utilized an average number based on historical orders, applied a three times multiplier on that base number, and then flagged an order if it exceeded that multiplier. From 2007 forward, an order would have been flagged only if it exceeded that multiplier for two consecutive months. The formulas were not scaled to the size of the community served. Nor were they informed by geography, population, news reports, local information (provided by pharmacists or news reports), outside investigation, or any form of human input that would actually be effective at slowing the flow of opioids into the illegal drug market in Tennessee. Instead, by setting these thresholds artificially high, Walgreens ensured that it would keep shipping orders below the threshold even though it should have halted those orders (rather than fill them).

303. Even at the exceedingly high threshold it had set, Walgreens still identified thousands of orders each week that hit that threshold. Those orders were obviously suspicious. Yet

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[138] Jenn Abelson, Aaron Williams, Andrew Ba Tran, & Meryl Kornfield, *At Height of Crisis, Walgreens Handled Nearly One in Five of the Most Addictive Opioids*, Wash. Post, Nov. 7, 2019, https://www.washingtonpost.com/investigations/2019/11/07/height-crisis-walgreens-handled-nearly-one-five-most-addictive-opioids/.
[139] *Id.*
[140] *Id.*

rather than halt the orders, ***Walgreens elected to ship them***. By shipping orders that Walgreens itself had identified as suspicious, it committed an act intended to facilitate the distribution of drugs into the illegal market.

304. Walgreens then waited until ***after*** shipping the orders to report them to anyone. By waiting until after filling an order to report it, Walgreens was able to facilitate the flow of drugs into Tennessee's illegal market.

305. In September 2012, the DEA issued an immediate suspension order ("ISO") for Walgreens' Schedule II distribution facility in Jupiter, Florida.[141] In the ISO, the DEA found that Walgreens' distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The ISO made the following findings:

a. In violation of its duty report under 21 CFR 1301.74 and a 2007 letter from the DEA, Walgreens had not reported suspicious orders as they were discovered, but instead had shipped the orders without due diligence to determine if the order was actually being made to serve legitimate medical needs;

b. Even though the facility served 12 states and Puerto Rico, the formula was the same regardless of a pharmacy's location, the population it serves, or the number of other pharmacies in the area;

c. Walgreens had failed to maintain an adequate suspicious order reporting system, ignored readily identifiable orders and ordering patterns that obviously reflected diversion at Walgreens pharmacies; and

d. Walgreens had distributed large amounts of opioids to pharmacies that it knew or should have known were dispensing the drugs to fill prescriptions that were not intended to serve a legitimate medical purpose.

306. Despite these and other warnings, Walgreens continued to commit acts intended to facilitate the distribution and dispensing of drugs by its pharmacies into the illegal market. It has

141 https://www.dea.gov/press-releases/2012/09/14/dea-serves-suspension-order-walgreens-distribution-center-jupiter-florida.

admitted that it is unaware of ever performing a due diligence review ***before*** shipment on orders listed on its Suspicious Drug Control Order report.

307. At the distribution center level, Walgreens purposely designed its system simply to supply whatever quantities of drugs its pharmacies requested, rather than to identify red flags of potential diversion.

308. Moreover, when Walgreens purported to implement anti-diversion measure in 2010 (for the first time), it designed the program to have significant holes. For years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Cardinal and AmerisourceBergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, effectively permitting double dipping. Walgreens stores also could transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, allowing transfer for which Walgreens' SOM system did not account. Stores could also place ad hoc "PDQ" (short for "pretty darn quick") orders for controlled substances outside of their normal orders days and outside of the SOM analysis and limits. Walgreens even could remove a store entirely its from SOM review.

309. Furthermore, at times when a store would submit an order that exceeded Walgreens' exceedingly high threshold, Walgreens would reduce the order to the threshold and ship it without conducting further investigation into why its pharmacies were making suspicious orders.

310. Walgreens also intentionally understaffed the department that was supposed to conduct diligence and intentionally did not give that group proper training. Despite thousands of orders being flagged each week (even under Walgreens' improperly high threshold), Walgreens

officials reviewed only a small fraction. It therefore continued to ship even those orders that it had identified as suspicious.

311. In November 2012, Walgreens simply began reducing orders down to threshold rather than halting the orders, investigating them, and reporting them to an appropriate official.

312. According to Walgreens witnesses, the company did not confirm a single suspicious order that it shipped to its stores.[142]

313. Walgreens has been repeatedly cited and penalized for shipping without effective controls against diversion. For example, in April 2013, it agreed to a then-record $80 million settlement with the DEA to resolve allegations that it had shipped oxycodone and other prescription painkillers that were diverted into the black market. The agreement mandated that, at a corporate level, Walgreens had to maintain a "Department of Pharmaceutical Integrity, a Suspicious Order Monitoring system, remove controlled substance from the calculation of bonuses for pharmacists and technicians, and verify prescribers' DEA numbers to ensure their validity. Despite these warnings, Walgreens continued to violate its responsibilities as a Tennessee registrant.

314. In particular, Walgreens' conduct facilitated the illegal distribution of opioids into the black market in Tennessee.

315. Even when pharmacies did hit internal limits imposed by Walgreens, "they could still transfer pills from other stores or order from outside suppliers[,]"[143] Walgreens officials intentionally authorized pharmacies to exceed the internal limits to maintain sales volume.

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[142] Bratton 65:20-66:11.
[143] Abelson, et al., supra note ___.

316. "Pharmacies could also find workarounds by placing special PDQ orders, meaning 'pretty darn quick,' from Walgreens internal network[,]"[144] a technique used repeatedly by Walgreens pharmacies in Tennessee. In 2012, Walgreens suggested forbidding PDQ orders for oxycodone products.[145] Pharmacy executive Kermit Crawford vehemently objected to the proposed change, writing, "I was not under the impression this was a done deal. Concerned we are 'all or none.' We have to do what's right for patients also."[146]

317. Walgreens' internal records showed that its pharmacies continued to operate in a manner that continued to supply opioid products to the illegal drug market in Tennessee, which included filling suspicious orders for pharmacies located in Tennessee, including areas that Walgreens had identified as at high risk of diversion.

318. Walgreens knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Walgreens is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Walgreens knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids. Walgreens also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of opioids to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

319. Also, Walgreens knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing/dispensing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales

[144] Abelson, et al., supra note ___.
[145] Abelson, et al., supra note ___.
[146] Abelson, et al., supra note 192.

representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for clearing suspicious orders for prescription opioids; and (iii) permitting and directing SOM personnel to prioritize clearing orders over reporting them.

4. Walmart Knowingly Fueled the Illegal Opioid Market

320. From 2000 to approximately May 2018, Walmart self-distributed tens of millions of shipments of controlled substances to Walmart-branded and Sam's Club-branded pharmacies. Throughout the period from 2012 to 2018, Walmart was the largest self-distributor in the country for oxycodone, hydromorphone, and hydrocodone in terms of both dosage units and grams.

321. Because Walmart acted as its own distributor, it had access to extensive data and other information that independent distributors would not ordinarily have. In particular, Walmart had a wealth of dispensing information that gave it the ability to investigate the circumstances underlying orders for controlled substances. Walmart had data about individuals who filled controlled-substance prescriptions at its pharmacies, the identities of medical providers who were prescribing controlled substances for those individuals, and reports from its own pharmacists raising concerns.

322. Despite having information about how often and how much Walmart-branded pharmacies and Sam's Club-branded pharmacies ordered from third-party distributors, Walmart did not account for these orders and shipments in its SOM program.

323. In November 2010, Walmart adopted Pharmacy Manual 21-402 ("Controlled Substance Monitoring"). This policy simply required certain Walmart employees to review a monthly report, known as a "control drug stock exception report," after the controlled substances had been shipped to the pharmacies and identify any controlled substances that constituted more

than 3.99% of a pharmacy's total controlled and non-controlled substance purchases during the prior month.

324. Under Pharmacy Manual 21-402 (November 2010), Walmart failed to detect many unusual orders. First, the monthly reports did not identify specific controlled substance orders that were unusually large. Instead, the reports aggregated all shipments of particular controlled substances and then compared those aggregated totals to see if they exceeded 3.99% of a pharmacy's total shipments that month. As a result, many unusually large orders were not flagged because they were not subsumed in the aggregated totals. Second, the policy did not require Walmart to flag any orders that were otherwise suspicious (e.g., exhibiting an unusual frequency or unusual pattern).

325. Pharmacy Manual 21-402 (November 2010) did not describe these aggregated totals as "suspicious orders" or even state that Walmart was required to detect and report suspicious orders to DEA.

326. In a June 12, 2014 email, Walmart attached a risk assessment in which it observed that its system for monitoring suspicious orders was an "existing risk" and "emerging risk" for which it had "no processes in place." Walmart's own assessment was that the risk that its pharmacies would place suspicious orders with its own distribution centers was "likely," the second-highest of five levels on Walmart's scale of likelihood of risks.

327. In July 2014, Walmart revised Pharmacy Manual 21-402 and titled the revised policy "Evaluating Orders of Interest and Suspicious Order Reporting." Unlike the 2010 version of the policy, Pharmacy Manual 21-402 (July 2014) instructed compliance unit personnel to evaluate individual orders as they were placed—rather than monthly aggregated totals after

Walmart's distribution centers had already shipped the controlled substances—and report any suspicious orders to DEA.

328. Pharmacy Manual 21-402 (July 2014) called for Walmart first to identify "orders of interest" from among all controlled substance orders, and then to investigate those "orders of interest" to determine whether they were indeed "suspicious orders" subject to reporting to DEA.

329. Both steps of this system failed. The criteria Walmart adopted for flagging "orders of interest in the first instance were plainly inadequate, allowing many suspicious orders to evade any scrutiny. And Walmart routinely failed to investigate orders that were flagged as "orders of interest" to ascertain whether they were suspicious, prioritizing expeditious distribution of controlled substances to meet its pharmacies' and pharmacists' demands over compliance with state and DEA regulations.

330. Walmart failed to detect and report at least hundreds of thousands of suspicious orders of controlled substances. Over an approximately four-year period from 2013 to 2018, a time during which Walmart shipped an estimated 37.5 million controlled-substance orders to its pharmacies, it reported only 204 suspicious orders to the DEA—in other words, almost none. By comparison, during the same time period, Walmart's back-up distributor McKesson Corporation, which filled orders only when Walmart could not, reported to the DEA more than 13,000 suspicious orders from Walmart pharmacies.[147]

331. Walmart knowingly entered and participated in the illegal drug market in Tennessee and the Baby Doe Plaintiffs' community. Walmart is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Walmart knew that such

[147] Despite even reporting that many (and that is just for the single customer Walmart), in 2017, McKesson was fined $150,000,000 by the DEA for its systemic failure to report suspicious orders during roughly the same period that Walmart reported only 204.

inflated prescribing necessarily reflects improper prescribing and diversion of opioids. Walmart also knowingly participated in the illegal drug market in the Baby Doe Plaintiffs' community by supplying quantities of opioids to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

332. Also, Walmart knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing/dispensing of opioids in Tennessee and the Baby Doe Plaintiffs' community, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for clearing suspicious orders for prescription opioids; and (iii) permitting and directing SOM personnel to prioritize clearing orders over reporting them.

E. The Pill Mill Defendants Have Illegally Trafficked Prescription Opioids in and Around the Baby Doe Plaintiffs' Community, Aided by the Producer Defendants, the Distributor Defendants, and the Pharmacy Chain Defendants

1. Timothy Abbott Fueled the Illegal Drug Market by Unlawfully Prescribing Opioids and Operating a Pill Mill

333. Defendant Timothy Abbott was a podiatrist who practiced in Davidson County until he was indicted on criminal drug charges in April 2019.

334. Abbott was not a legitimate doctor but rather "an easy source of addictive and dangerous narcotics." His clinic was "extremely dirty," containing only a single exam room with "old and rusty equipment." The Department of Justice described it as "a clinic where any given patient, on any given day, could expect to receive a prescription for opioids by just asking for one."

335. Indeed, Abbott's prescribing numbers back this description up: between 2016 and 2018, he was the highest-prescribing podiatrist in the state, writing 3,689 prescriptions for hydrocodone and oxycodone. On average, podiatrists wrote between 100 and 200 opioid

prescriptions during the same time period, with the next-highest prescribing podiatrist writing 1,045 opioid prescriptions, over 2,500 less than Abbott.

336. On April 10, 2019, Abbott was indicted on 7 counts of unlawful distribution of opioids as a result of the Appalachian Regional Prescription Opioid Strike Force's investigation.

337. On February 26, 2020, Abbott pleaded guilty to all 7 counts, Abbott admitted that he "prescribed Schedule II controlled substances, including hydrocodone, for his patients outside the usual course of professional practice and without a legitimate medical purpose." Abbott further admitted that, from April 26, 2013, to February 25, 2019, he unlawfully prescribed hydrocodone on at least 44 separate occasions.

338. On June 9, 2020, following his guilty plea, the Tennessee Board of Podiatric Medical Examiners revoked Abbott's license. As grounds for this revocation, the Board specifically cited: (a) that Abbott's opioid prescriptions were in amounts and/or for durations that were not medically necessary, advisable or justified; (b) Abbott had failed to perform proper diagnostic testing prior to prescribing opioids; (c) that Abbott failed to document his controlled substance prescriptions; and (d) that Abbott's opioid prescribing was in a non-therapeutic manner, was not justified, was not medically necessary, and was not for any legitimate purposes.

339. Abbott's conduct constituted knowing participation in the illegal drug market, including but not limited to: knowingly supplying suspicious quantities of opioids to suspect patients who were showing signs of addiction or participation in diversion; knowingly supplying suspicious quantities of opioids which were not medically justified; knowingly supplying suspicious quantities of opioids which quantities necessarily reflected diversion; and knowingly failing to implement effective controls and procedures to guard against diversion of opioids.

2. Cindy Scott Fueled the Illegal Drug Market by Unlawfully Prescribing Opioids and Facilitating the Operation of Pill Mills

340. Defendant Cindy Scott is a registered nurse and advanced practice nurse who has practiced in Davidson County.

341. Scott was widely known by the pharmaceutical industry and medical community at-large as a prolific prescriber of opioids. Between 2012 and 2014, Scott was identified by the Tennessee Department of Health ("TDOH") as one of the Top 50 prescribers of controlled substances in the state.

342. When opioid producers promoted their branded opioids through their sales forces, Scott was a frequent and favorite target. She was so important to Endo's Opana ER business that an Endo sales representative enlisted the help of his district manager to sit down with her when he heard that she was considering writing prescriptions for only generic opioids.

343. Scott has worked for pill mill after pill mill, including the Cookeville Center for Pain Management (from May 2012 to January 2014) and HopeHealth, LLC in Nashville (from January 2014 until HopeHealth's pain management certificate was suspended by the TDOH).

344. The Cookeville Center for Pain Management (and its management company and owner) was required to pay more than $1.45 million to resolve a civil whistleblower suit for, as then-Attorney Jeff Sessions put it, "overprescribing opioids…in [its] own financial interests, at the expense of the patients' best interests."

345. The TDOH similarly suspended HopeHealth's pain management certificate for its failure to retain a medical director. The TDOH's suspension order explained that HopeHealth could not keep a medical director because:

> [Medical Directors had] serious concerns…with the amount of, and frequency with which patients were being provided, controlled substances by [HopeHealth] and its providers, the refusal of [HopeHealth] and its providers to follow [Medical Directors'] instructions about tapering the amount of opioids and benzodiazepines being prescribed to certain patients, the inadequate and inconsistent patient charting

> by the providers of [HopeHealth], and the unwillingness of [HopeHealth] and its providers to implement protocols [they] felt were necessary and appropriate.

346. Scott was an integral part of these pill mills and their illegal operations. She explained to clinic employees that patients "should never expect to see a doctor on-site." Scott would submit false diagnoses "that would yield the prescription…the patient wanted (i.e., a medication with high 'street' value)" and was instrumental in teaching other employees how to do the same.

347. Scott's unscrupulous and rampant opioid prescribing drew the attention of the TDOH. On November 29, 2016, Scott was disciplined by the TDOH for her "haphazard and unprofessional prescribing practices." The TDOH's consent order cited numerous violations, including Scott's failure to conduct adequate examinations to justify her opioid prescriptions, Scott's failure to appropriately document her treatment, and Scott's failure to inquire into patients' substance abuse history or their potential for substance abuse.

348. The TDOH concluded that Scott's opioid "prescribing…was non-therapeutic in nature, neither justified nor medically necessary for the patients' diagnoses, and not for a legitimate purpose." The TDOH explained that Scott "often prescribed monthly prescriptions to individual patients exceeding a daily dosage of five hundred (500) morphine milligram equivalents…include[ing] inappropriate combinations of long and short acting opioids often combined with high amounts of benzodiazepine and/or carisoprodol.

349. The TDOH ultimately placed her RN license on probation for 5 years, suspended her APN license for 2 years, and required that she surrender her DEA registrations "for all schedules of controlled substances and agree[] to not seek reinstatement of such DEA privileges for a period of five years."

350. Scott's unlawful actions also drew the ire of the Department of Justice. On January 22, 2018, Scott entered into a settlement agreement with the United States and the State of Tennessee to settle civil claims relating to "controlled substance prescriptions prescribed, ordered, and/or dispensed by Scott to patients as part of a prescribing pattern that was not for a legitimate medical purpose." In addition to a $32,000 settlement payment, Scott agreed to surrender her DEA registration and not seek reinstatement until December 1, 2021.

351. Scott's conduct constituted knowing participation in the illegal drug market, including but not limited to: knowingly supplying suspicious quantities of opioids to suspect patients who were showing signs of addiction or participation in diversion; knowingly supplying suspicious quantities of opioids which were not medically justified; knowingly supplying suspicious quantities of opioids which quantities necessarily reflected diversion; and knowingly failing to implement effective controls and procedures to guard against diversion of opioids.

3. Hemal Mehta and Heather Marks, individually and in concert with one another, Fueled the Illegal Drug Market by Unlawfully Prescribing Opioids and Operating a Pill Mill

352. Hemal Mehta is a doctor practicing in Davidson County and the larger Nashville Metropolitan area. Heather Marks is an Advanced Practice Registered Nurse who practiced under Mehta's supervision from 2015 through 2018.

353. Mehta was one of the area's most prolific opioid prescribers and a favorite target of the Producer Defendants. From 2008 until it stopped detailing doctors at the end of 2016, Endo alone called on Mehta over 300 times.

354. Mehta was such a devout prescriber of Endo products that Endo nominated him to be one of its key opinion leaders wherein it would pay him to evangelize to other potential prescribers the supposed benefits and safety of Opana ER.

355. However, Mehta and Marks were not issuing these opioid prescriptions legally. For years, Mehta and Marks's prescribing habits were scrutinized by the State of Tennessee and, eventually, the federal government.

356. On April 10, 2019, Marks was indicted as part of the Appalachian Regional Prescription Opioid Strike Force for the unlawful distribution of oxycodone and oxymorphone.

357. Further investigation revealed that Marks was not acting alone. The Strike Force's investigation revealed that Marks was helping Mehta run a pill mill for the purpose of "distribut[ing] and dispens[ing] Schedule II controlled substances, including oxycodone and oxymorphone, without a legitimate medical purpose and outside the usual course of professional practice."

358. On October 23, 2019, Mehta was added as a co-defendant in a superseding indictment, which alleged that Mehta and Marks both conspired to unlawfully distribute opioids, and from December 22, 2016, to April 25, 2018, Mehta and Marks unlawfully distributed oxymorphone and oxycodone on at least nine separate occasions.

359. Mehta and Mark's conduct, both individually and in concert, constituted knowing participation in the illegal drug market, including but not limited to: knowingly supplying suspicious quantities of opioids to suspect patients who were showing signs of addiction or participation in diversion; knowingly supplying suspicious quantities of opioids which were not medically justified; knowingly supplying suspicious quantities of opioids which quantities necessarily reflected diversion; and knowingly failing to implement effective controls and procedures to guard against diversion of opioids.

4. James Maccarone Fueled the Illegal Drug Market by Unlawfully Prescribing Opioids and Operating a Pill Mill

360. James Maccarone was a doctor who operated a pill mill in Clarksville, Tennessee until his arrest on federal drug charges in July 2021.

361. Maccarone's pill mill was notorious for the ease with which a patient could obtain a prescription for opioids, such that patients would travel from hundreds of miles away to obtain opioid prescriptions.

362. Although Maccarone's pill mill was located nearly 60 miles away in Clarksville, he was one of the highest prescribers of opioids for a number of Davidson County pharmacies.

363. On July 22, 2021, Maccarone, along with three other individuals, was indicted for unlawfully distributing and conspiracy to distribute narcotics, including oxycodone, oxymorphone, and methadone from at least July 2016 through March 2021.

364. On January 24, 2022, Maccarone pleaded guilty to conspiracy to unlawfully distribute controlled substances, to wit—opioids.

365. Maccarone admitted that his opioid prescribing "repeatedly failed to adhere to accepted professional standards for prescribing controlled substances for the treatment of chronic pain," and that he issued prescriptions to patients whom "exhibited obvious signs of drug diversion and abuse."

366. Maccarone further admitted that some of his patients "subsequently distributed the drugs obtained from those prescriptions to others" and that they "understood that if they paid the high case fees [Maccarone] charged, [Maccarone] would prescribe them oxycodone, oxymorphone, and other controlled substances that could be abused or sold for a profit.

367. Maccarone admitted that he unlawfully wrote prescriptions for at least 32,722 oxycodone pills and 12,258 oxymorphone pills.

368. Maccarone's conduct constituted knowing participation in the illegal drug market, including but not limited to: knowingly supplying suspicious quantities of opioids to suspect patients who were showing signs of addiction or participation in diversion; knowingly supplying suspicious quantities of opioids which were not medically justified; knowingly supplying suspicious quantities of opioids which quantities necessarily reflected diversion; and knowingly failing to implement effective controls and procedures to guard against diversion of opioids.

5. Pardue's Pharmacy Fueled the Illegal Drug Market Repeatedly Making Suspicious Orders for Opioids and Filling Opioid Prescriptions for Notorious Regional Pill Mills and Problem Prescribers

369. Pardue's Pharmacy ("Pardue's") is an independent pharmacy operating in Davidson County.

370. Pardue's has long been one of Davidson County's highest dispensers of opioids, enthusiastically accepting prescriptions from notorious pill mill prescribers. Many of Pardue's top opioid prescribers have since been arrested, lost their license, or are now practicing on restricted licenses, Cindy Scott (whose unlawful conduct was detailed above).

371. Pardue's would regularly fill opioid prescriptions for patients exhibiting obvious signs of abuse, addiction, and/or diversion. Pardue's even witnessed these patients abusing opioids before they had left the premises, in one instance seeing a patient snort an opioid in the parking lot that it had just dispensed.

372. Nonetheless, Pardue's endeavored to meet the demand of these criminal prescribers and drug dealers by consistently ordering above its threshold for opioid products. If an order was rejected, Pardue's would demand an increase to its opioid thresholds and threaten to take its considerable book of business to another distributor if their demands were not met.

373. In order to avoid scrutiny and keep the opioids flowing, Pardue's worked in concert with its distributors to "game the system" by requesting their opioid thresholds (which are not supposed to be revealed to customers) and using that information to pattern its opioid orders such that the orders would not trigger a distributor's obligation to report the orders as suspicious.

374. Using these ordering tactics to keep up with the demand of its suspicious prescribers and clientele, from 2006 through 2014 alone, Pardue's was able to purchase approximately 296,304,000 MMEs of opioids.

375. Pardue's did not even take the most basic precautions to prevent these opioids from ending up on the black market. A 2015 audit by AmerisourceBergen, its primary distributor, revealed just how little Pardue's cared about its responsibility to maintain effective controls to prevent diversion, revealing such glaring red flags as:

- Having no formal, written pharmacy due diligence policy with regard to dispensing controlled substances;
- Pharmacists dispensing duplicate immediate-release opioids to the same patient(s) without noting/confirming that an established and legitimate clinical need;
- Pharmacists dispensing the "Holy Trinity" cocktail without noting/confirming an established and legitimate medical need;
- Dispensing disproportionate amounts of controlled substances, specifically Schedule II controlled substances (estimated to be between 80% to 90% of all prescriptions filled);
- Dispensing a disproportionate amount of prescriptions paid with cash (Pardue's reported 60% of its patients were cash-pay);
- Security concerns due to prior incidents involving significant thefts of controlled substances, including opioids such as Opana ER; and
- The Pharmacist-in-Charge's state pharmacist's license being on probation.

The PIC even told the auditor that he was "not comfortable with the amount of controlled substances being dispensed" and that he was "thinking about quitting." This PIC did not quit and remains Pardue's PIC to this day.

376. However, despite these obvious red flags of diversion (and the personal trepidations about the legality of its conduct), Pardue's continued to purchase and dispense opioids in obscene quantities, purchasing an additional 1,192,711 opioid pills from June 26, 2015 through January 6, 2017.

377. Pardue's conduct constituted knowing participation in the illegal drug market, including but not limited to: knowingly supplying suspicious quantities of opioids to suspect patients who were showing signs of addiction or participation in diversion; knowingly supplying suspicious quantities of opioids which were not medically justified; knowingly supplying suspicious quantities of opioids which quantities necessarily reflected diversion; and knowingly failing to implement effective controls and procedures to guard against diversion of opioids.

F. The Drug Producer Defendants Helped Create the Illegal Drug Market

1. In the 1990s, the Drug Producer Defendants Knew that Using Opioids for Non-Malignant Pain Creates a Serious Risk of Abuse and Diversion Yet Encouraged Opioid Sales and Distribution Practices That It Knew Have Those Effects

378. As stated by Tennessee's Commissioner of Health Dr. John Dreyzehener, "***in the 1990's, MDs started prescribing opioids in large volume to treat [nonmalignant] pain which has caused an opioid addiction problem.***"[148] Douglas Varney, Commissioner of the Tennessee Department of Mental Health, speaking at a meeting of the Governor's Working Group, similarly

[148] Tenn. Dep't of Mental Health and Substance Abuse Services, *Opioid Abuse Reduction Act Working Group*, at 22 (Nov. 10, 2015) [hereinafter *Working Group Report*] (emphasis added).

concluded that "***[b]asically we are dealing with the fallout from the medical profession overprescribing opioids.***"[149]

379. Up until the mid-1990s, physicians prescribed opioids primarily to cancer patients and persons recovering from surgery. Fearful of the addictive qualities of opioids, physicians would not generally prescribe them for long term chronic pain. As detailed in a review of the development of the opioid crisis published in the 2015 Annual Review of Public Health, "[p]rior to the introduction of OxyContin [by Purdue in 1995], many physicians were reluctant to prescribe OPRs [opioid pain relievers] on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence."[150]

380. This research confirmed the mid-1990s consensus of medical providers regarding the dangers of opioids. According to the Agreed Statement of Facts signed by Purdue in connection with its 2007 guilty plea to federal criminal charges for misbranding OxyContin: "During the period February through March 1995, Purdue supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain… '***[t]he biggest negative of [OxyContin] was the abuse potential.***'"[151]

381. When branded opioids were introduced to the U.S. market, including Tennessee, the Producer Defendants carefully evaluated physicians' concerns about the risks of addiction associated with opioids and embarked on a highly successful campaign to convince physicians that opioids created minimal risk of addiction. Upon information and belief, the Producer Defendants

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[149] *Id.* (emphasis added).
[150] Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 562. (2015).
[151] Information as to Purdue Frederick Co., Inc., U.S.A v. Purdue Frederick Co., Inc., No. 1:07-cr-00029 W.D. Va. May 10, 2007, ECF No. 5-2 at ¶19 (emphasis in original).

knew that, if its efforts were successful, many people would become addicted to prescription opioids and that, as a consequence, abuse and illegal diversion would follow.

382. As the Producer Defendants' efforts demonstrated success in the form of rapid increases in opioid prescribing, other opioid producers joined in their efforts to expand the market for opioids.

2. The Drug Producer Defendants Funded "Key Opinion Leaders" to Spread Misinformation Regarding Opioids

383. The Producer Defendants engaged "key opinion leaders" to promote the use of their opioids in a variety of ways. Each Producer Defendant would pay a key opinion leader an honorarium each time he or she agreed to attend a variety of functions, from intimate meals with a single pain management clinic's staff to presenting at huge national and international symposia. Key opinion leaders were selected based on a number of criteria such as the prestige of their affiliated hospitals and the quantity of their published articles, but most importantly their willingness to promote the prescription of opioids.

3. The Drug Producer Defendants Funded Dr. Russell Portenoy, Who Facilitated the Widespread Distribution and Abuse of Opioids by Acting as a Vocal Proponent of Opioid Use

384. The Drug Producer Defendants funded and worked closely with Dr. Russell Portenoy, a physician who emerged as one of the industry's most vocal proponents of long-term opioid use.[152] According to a Wall Street Journal article, Portenoy essentially made it "his life's work" to campaign for the movement to increase use of prescription opioids.[153] To this end, speaking on Good Morning America in 2010, Portenoy stated categorically that "[a]ddiction, when

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[152] Thomas Catan & Evan Perez, *A Pain Champion has Second Thoughts*, wsj.com (Dec. 17, 2012). Available at: https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[153] *Id.*

treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted." This program was broadcasted across the country and, upon information and belief, was widely watched, including within Tennessee and in Plaintiffs' community. Portenoy, who himself is facing lawsuits for his work as a paid opioid pitchman, has now conceded that this promotion of opioids for chronic pain was "clearly the wrong thing to do."[154] He is on record stating: "I gave innumerable lectures in the late 1980s and 90's about addiction that weren't true."[155]

385. The Drug Producer Defendants paid Dr. Portenoy millions of dollars from 1997 to 2007 to continue publicizing information that they knew would continue to create opioid addicts and would fuel the secondary illegal market for opioids. For example, in approximately 2004, Endo published an education pamphlet edited by Dr. Portenoy, called *Understanding Your Pain: Taking Oral Opioid Analgesics*, which claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems."[156] In funding Dr. Portenoy, the Drug Producer Defendants yet again knowingly helped foster the growing population of opioids addicts and perpetuated the illegal opioids market that serviced them and which would carry forward into the late 2010's.

386. Endo and Teva both listed Dr. Portenoy as a "Key Opinion Leader" at various times.

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[154] *Id.*
[155] *Id.*
[156] http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

4. In December 2009, Endo Funded the Publication of Medical Education Materials Stating, *inter alia*, That "Addiction is Rare in Patients Who Have Become Psychologically Dependent on Opioids"

387. Aside from funding a pro-opioid pitchman, in December 2009, Endo also paid for medical education materials which: (1) reiterated the claim that "addiction is rare in patients who become psychologically dependent on opioids while using them for pain control"; (2) emphasized the need to individually evaluate each patient "as clinical trials [rejecting opioid treatment] are not designed to identify the best treatment regimen in a given situation to manage chronic pain"; and (3) urged use of opioids even for patients engaging in "aberrant behaviors" while setting the following extreme standard to be used to identify individual patients with addiction problems: "a patient exhibiting egregious behaviors that persist, despite repeated warnings and that require significant time and resources to manage, is likely to have a problem with abuse and possibly addiction." The materials further stated that "[a]n opioid trial is the only way a clinician can determine the efficacy and tolerability of a particular agent in a particular person."[157] In other words, the only way to rule out opioids for any given chronic pain patient was to give opioids a try. Upon information and belief, these materials were available to and/or were distributed to Tennessee physicians.

388. Upon information and belief, Endo funded the publication of these materials knowing that doing so would result in more opioid addicts and would promote the significant illegal market for opioids on which those addicts depended – and that precisely those effects were occurring nationwide, in Tennessee, and in the communities at issue in this case.

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[157] Anderson et al, "Opioid Prescribing: Clinical Tools and Risk Management Strategies, available at: https://mn.gov/boards/assets/Opioid_Prsecibing_Clinical_Tools_and_Risk_Management_Strategies.pdf_tcm21-366993.pdf.

5. The Drug Producer Defendants Funded the American Pain Foundation, Which Claimed (Among Other Things) That the Belief That "Opioid Pain Medications are Universally Addictive" was a Common Misconception

389. The Drug Producer Defendants also funded the American Pain Foundation ("APF"), which has been described by the President of Physicians for Responsible Opioid Prescribing as "a front for opioid manufacturers."[158] The APF's 2010 annual report details thousands of pro-opioid advertisements, public statements, letters, Facebook Posts, and similar communications. It states that: "Through online, print, radio, and television outlets, APF's local and national media outreach efforts secured 1,600 media stories on pain in 2010 – an increase of 1,255% from 2009. Reaching more than 600 million people with important pain-related messages, APF spokespeople and advocates provided education, information and assistance to people with pain and combated the negative stereotypes and stigmas associated with pain."[159] Upon information and belief, APF distributed the types of messages referenced in its 2010 Annual Report to physicians within Tennessee.

390. For example, in or around 2011, the APF published "Policymaker's Guide," which characterized the notion that "strong pain medication leads to addiction" as a "common misconception[]":

> Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines

[158] Charles Ornstein and Tracy Weber, *Patient Advocacy Group Funded by Success of Painkiller Drugs, Probe Fins*, washingtonpost.com, Dec. 23, 2011. Available at: https://www.washingtonpost.com/national/health-science-/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html.
[159] American Pain Fund 2010 Annual Report. Available at: https://archive.org/stream/277604-apf-2010-annual-report/277604-apf-2010-annual-report_djvu.txt.

> are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[160]

The guide describes "pain in America" as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . ***Misconceptions about opioid addiction.***"[161] It even characterizes as a "***myth***" that "***[c]hildren can easily become addicted to pain medications.***"[162] This message is just one example of the types of messages that APF published with substantial financial support from the Drug Producer Defendants.

391. Upon information and belief, the Drug Producer Defendants funded the APF and supported it with the intention and expectation that APF's messaging would continue to create more opioid addicts and necessarily result in more illegal abuse and distribution of opioids – and knowing that precisely those effects were occurring nationwide, in Tennessee, and in the communities at issue in this case.

G. Endo Also Independently Contributed to the Creation of the Illegal Market for Prescription Opioids Across the Country, Including Tennessee

1. Endo Operated and/or Sponsored Websites and Other Publications Stating, *inter alia*, That "Most Healthcare Providers Who Treat Patients With Pain Agree That Patients Treated With Prolonged Opioid Medications Usually Do Not Become Addicted"

[160] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5. Available at: http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited Dec 1, 2021).
[161] *Id.* at 6 (emphasis added).
[162] *Id.* at 40 (emphasis added).

392. Upon information and belief, on its website, www.opana.com, Endo included a claim that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medications usually do not become addicted."

393. In other materials, Endo further claimed that the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to being obtained through the illicit market. For example:

a. Endo sponsored a facially unaffiliated website, Painknowledge.com, available in Tennessee and elsewhere, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." The website further promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Painknowledge.com was run by the National Institute on Pain Control ("NPIC"), an APF initiative, and Endo's involvement was not disclosed on the website, by the NPIC, or by Endo; and

b. Similarly, *Exit Wounds*, a 2009 publication sponsored by Purdue and distributed by APF with grants from Endo, describes opioids as "under-used" and the "gold standard of pain medications" without referencing the risk of addiction, overdose, or injury. It notes that opioid medications "increase your level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The book also asserts that "denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards."

394. Upon information and belief, these websites and publications were available to physicians in Tennessee and to end users of opioids.

395. The guidelines of the U.S. Federation of State Medical Boards ("FSMB") referenced in *Exit Wounds* were actually created and published during a time that the FSMB itself received significant financial support from the Drug Producer Defendants. In a June 8, 2012 letter to the Senate Finance Committee, the FSMB disclosed the following payments it had received:

Defendant Endo paid FSMB a total of $371,620.00 from 2007 to 2009 and 2011 to 2012; and Defendant Teva paid FSMB a total of $180,000 from 2007-2008 and in 2011.[163]

396. The drug producer-sponsored FSMB guidelines warned physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and taught that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids" – which are, in fact, signs of genuine addiction – are all really just signs of "pseudoaddiction."[164] The FSMB guidelines defined "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[165] The guide became the seminal authority on opioid prescribing for the medical profession.

2. In 2012 and 2013, Endo Directed its Sales Associates to Claim That Reformulated Opana ER was Less Subject to Tampering Despite Knowing That Use of Opana ER was Still Likely to Foster Addiction

397. Endo further sought to minimize the perceived risk of abuse and addiction of its opioid product by downplaying the abuse-potential of a new version of Opana ER. In 2012, Endo replaced the original formulation of Opana ER with a new formulation ostensibly intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting. At that time, Endo asked the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, meaning that it was protected against manipulation that would allow users to snort or

[163] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.
[164] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, at 62 (Waterford Life Sciences 2007).
[165] *Id.*

inject it. It also sought permission to withdraw its previous approval for Opana ER in favor of its newer, purportedly safer version. Endo announced that it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence), which (if true) would have prevented generic copies of the original Opana ER.

398. While Endo's new version of Opana ER met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER.

399. Nevertheless, upon information and belief, Endo advised its sales representatives to market reformulated Opana ER as the only oxymorphone extended release tablets that are "designed to be" crush resistant. Endo did so to falsely imply that Opana ER actually was crush-resistant and that the crush-resistant quality would make Opana less likely to be abused.

400. Upon information and belief, in an internal Endo document from February 2013, an Endo consultant, after reviewing national data from substance abuse treatment facilities, reported that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant," and that there were reports of higher levels of abuse of reformulated Opana ER via injection.[166]

401. The Endo consultant's finding was consistent with the CDC's "Guideline for Prescribing Opioids for Chronic Pain – United States, 2016," which states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring

[166] *See, e.g., In re: Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228 (March 2016). Available at: https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals. [Hereinafter "NY AG Settlement"], ¶ 16 (quoting from an Endo document).

or preventing abuse."[167] The CDC further notes that the "abuse-deterrent" technologies, even when they work, "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[168]

3. In 2016, Endo Entered Into an Agreement With the State of New York to Cease Touting That Opana ER is Less Likely to Result in Addiction

402. Endo's conduct drew the attention of the Attorney General of the State of New York ("NY AG"), who opened an investigation into the company's promotional practices. In March 2016, the NY AG and Endo reached an agreement ending the investigation.[169] As part of that agreement, Endo agreed not to:

a. make statements that Opana ER or opioids generally are non-addictive;

b. make statements that most patients who take opioids do not become addicted, unless such statements are supported by competent and reliable evidence. If Endo believes that such evidence exists, it shall provide such evidence to the OAG at the time of initial dissemination of the statement, along with a copy of such statement;

c. make statements describing what most HCPs believe, unless such statements are supported by competent and reliable evidence. If Endo believes that such evidence exists, it shall provide such evidence to the OAG at the time of initial dissemination of the statement, along with a copy of such statement;

d. make statements that Reformulated Opana ER is, is designed to be, or is crush resistant, unless such statements are supported by the FDA-approved product labeling; and

e. use the term "pseudoaddiction" in any training or marketing.

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[167] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, at 22, March 18, 2016. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.
[168] *Id.*
[169] *See, e.g.*, NY AG Settlement.

H. Teva Also Contributed to the Illegal Prescription Opioid Market which Fuels Tennessee's Opioid Epidemic

1. Teva Pushed Opioid Drugs for Unapproved Purposes

403. As described herein, Teva is knowingly participating in the distribution chain of illegal opioids in Tennessee and in Baby Doe Plaintiffs' community by various means. Among other acts alleged herein, its prodigious supply of opioids into East Tennessee far exceeds the quantity of drugs that could be used legally and for medically necessary purposes, and necessarily reflects knowing participation in the widespread and notorious illegal opioids market in Plaintiffs' community. These facts alone establish knowing participation in the chain of distribution of illegal drugs in East Tennessee. Teva's knowing participation in this illegal drug market is reinforced by its own historic efforts to increase the size of that market and/or to capture an increasing share of it from year to year.

404. According to a DOJ press release that summarizes Teva's guilty plea for criminal violations of the Food and Drug Act, Teva trained its sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of Teva opioids and funded Continuing Medical Education ("CME") Courses to promote off-label uses. Specifically, the DOJ stated:

> From 2001 through at least 2006, ***[Teva] was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. [Teva] also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.***[170]

[170] Press Release, U.S. Department of Justice, Pharmaceutical Company Teva To Pay $425 Million for Off-Label Drug Marketing (Sept. 29, 2008). Available at: https://www.justice.gov/sites/default/files/civil/legacy/2014/01/09/Cephalon%20Press%20Release.pdf (emphasis added).

405. As a result of this unlawful marketing of Actiq, almost 90% of Actiq prescriptions were to patients for off-label, non-cancer use.

406. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Teva's unlawful practices:

> This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.[171]

2. Teva Funded Pro-Opioid Publications and Presentations

407. In addition to its direct marketing, Teva indirectly marketed through third parties to change the way doctors viewed and prescribed opioids - disseminating the messages that opioids were safe for the treatment of chronic, long-term pain, that they were non-addictive, and that they were under-prescribed to the detriment of patients who were needlessly suffering. Teva did so by sponsoring pro-opioid front groups, prescription guidelines, articles, and CMEs, and Teva paid physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

408. Through its sponsorship of the FSMB's "Responsible Opioid Prescribing: A Physician's Guide," Teva continued to encourage the prescribing of opioid medication to "reverse ... and improve" patient function, attributing patients' displays of traditional drug- seeking behaviors as merely "pseudoaddiction."

[171] *Id.*

409. Teva sponsored APF's guide, which warned against the purported under-prescribing of opioids, taught that addiction is rare and suggested that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.

410. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues:

> ***Pain management is a fundamental human right*** in all patients not only with acute postoperative pain but also ***in patients suffering from chronic pain***. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.[172]

411. Teva also sponsored, through an educational grant, the regularly published journal Advances in Pain Management. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik, Dr. Kenneth L. Kirsh, and Webster, all advancing the safety and efficacy of opioids. In an article titled "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expresses disdain for the prior 20 years of opioid phobia.

412. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh state: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-

[172] Mohamed A. Elkersh & Zahid H. Bajwa, Highlights From the American Academy of Pain Medicine 24th Annual Meeting, 2(1) Advances in Pain Management 50-52 (2008) (emphasis added).

recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[173]

413. In November 2010, Fine and others published an article presenting the results of another Teva-sponsored study, concluding that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[174] They also conclude that the number of abuse-related events was "small."[175]

414. From 2000 forward, Teva has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Fine, Passik, Kirsh, and others.

I. From 2012-2017, the Drug Producer Defendants Helped Funnel Millions of Dollars to Advocacy Groups that Promoted Opioid Use

415. On February 13, 2018, Senator Claire McCaskill, released a report showing that Purdue and other producers funneled over $10 million to 14 advocacy groups and affiliated doctors who took "industry friendly positions," which included issuing medical guidelines promoting opioids for chronic pain, lobbying to defeat or include exceptions to state limits on opioid

[173] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization,* 2(1) Advances in Pain Management 9-16 (2008).
[174] Perry G. Fine, et al., Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).
[175] *Id.*

prescribing, and criticizing prescribing guidelines from the U.S. Centers for Disease Control and Prevention. The Report states that as these industry-funded entities and affiliated physicians:

> [o]ften echoed and amplified messages favorable to increased opioid use – and ultimately the financial interest of opioid manufacturers. These groups have issued guidelines and policy minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over-prescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain – the first national standards for prescription opioids and a key federal response to the ongoing epidemic.
>
> The fact that these same manufacturers provided millions of dollars to the group described [in this report] suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals this way, the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.[176]

J. The Drug Producer Defendants Knowingly Fostered Opioid Addiction and Fueled the Illegal Opioids Market in Which They are Now Knowingly Participating

416. The Drug Producer Defendants' promotion of opioids gave rise to and fueled the illegal drug market that existed in Plaintiffs' community during all periods relevant to this suit. Their representations regarding the risks of opioids and actions taken to push opioids through aggressive marketing of their collective message contributed to the market for both illegally prescribed opioids and for diverted opioids (and heroin for those addicts who could no longer obtain or afford prescription opioids).

[176] Fueling an Epidemic, Report Two: *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Group*, U.S. Homeland Security & Governmental Affairs Committee, Ranking Member's Office, https://www.publicintegrity.org/2018/02/12/21568/021218-mccaskill-report.

417. As set forth in the examples above, the Drug Producer Defendants operated websites and/or funded third party physicians, organizations, and websites that all pushed the message that opioids were not highly addictive and/or were appropriate for long-term use to treat chronic pain. The Drug Producer Defendants chose not to fund any organizations and third parties who promoted the contrary (and scientifically supported) message that opioids were highly addictive and not suitable for long-term use to treat chronic pain. It also chose not to pull funding from the pro-opioids organizations. The Drug Producer Defendants made these choices knowing and expecting that by doing so, the opioids market would continue to expand and continue to create more opioid addicts dependent on the illegal diversion of their products.

418. Each of their actions benefitted the other by creating legions of opioid addicts desperate to obtain opioids from any producer's line. The dramatic rise in opioid prescriptions, and associated overdoses, other related health problems, and NAS births (as detailed below) since the commencement of the Drug Producer Defendants' campaign in the mid-1990's shows the scope of the illegal drug market knowingly created by those defendants.

419. Speaking before the House Opioid Task Force in 2017, Dr. Michael Baron of the Tennessee Board of Medical Examiners summed up the cumulative effect of the opioid producers' multi-year campaign:

> We came out with what I call 'Generation O.' A whole generation of physicians that were taught it's ok to prescribe opiates, that they're safe, and that it's what the patient wants. But we bypassed evidence-based medicine. The whole medical system was hijacked by industry and really agreed.
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> [***]
>
> The triggers of the opioid epidemic were really the pharmaceutical industry and pain experts that were on the payroll of the pharmaceutical industry. And they preached that opioids are safe and effective for chronic, non-cancer pain, the risk

of addiction is rare, and opioid therapy can be easily discontinued, all of which is nonsense.[177]

K. The Drug Producer Defendants, the Drug Distributor Defendants, and the Pharmacy Chain Defendants Engaged in a Conspiracy to Profit from the Illegal Opioid Market by Any Means Necessary Which Exacerbated the Opioid Epidemic

420. The Drug Producer Defendants, the Distributor Defendants, and the Pharmacy Chain Defendants were engaged in a conspiracy to circumvent state and federal laws intended to minimize the diversion of opioids.

421. Through chargeback data, the Drug Producer Defendants had visibility into the extravagant opioid orders being placed by retail pharmacies, including those owned and operated by the Pharmacy Chain Defendants. Instead of reporting these orders to law enforcement and refusing to honor these rebates, the Drug Producer Defendants almost always continued to supply the Pharmacy Chain Defendants and others with opioids at a discounted rate to maximize their profits.

422. The Distributor Defendants were in regular contact with the Drug Producer Defendants about potentially suspicious pharmacies; but as long as the Drug Producer Defendants continued to honor chargebacks, the Distributor Defendants continued to fill these pharmacies' suspicious orders, especially if the pharmacy at issue was one of the Pharmacy Chain Defendants.

423. The Pharmacy Chain Defendants knew that the Distributor Defendants fiercely competed with one another for their substantial books of business. As a prerequisite to gifting the Distributor Defendants their accounts, the Pharmacy Chain Defendants would demand that all of their locations be exempted from the Distributor Defendant's SOM system until their exorbitant monthly orders of opioids would not be identified as "suspicious" by the Distributor Defendants.

[177] House Opioid Task Force, February 23, 2017.

Even when an order for a Pharmacy Chain Defendant was identified by a Distributor Defendant's SOM system, the Distributor Defendant would expediate a threshold increase to clear the order. The Distributor Defendants were so worried about losing the Pharmacy Chain Defendants' business that they would proactively reach out to the Pharmacy Chain Defendants when their SOM team saw a Pharmacy Chain Defendant location nearing its threshold for opioids.

424. As self-distributors of opioids themselves at certain points, the Pharmacy Chain Defendants understood that the Distributor Defendants had obligations to monitor for suspicious orders, but nevertheless demanded (and received) threshold increases for what the Pharmacy Chain Defendants clearly knew were suspicious orders for opioids. The Drug Producer Defendants witnessed and enabled these unlawful ordering tactics by continuing to grant chargebacks for the Pharmacy Chain Defendants, and encouraged the Distributor Defendants to keep the opioids flowing to these suspicious pharmacies.

425. The Drug Producer Defendants, the Distributor Defendants, and the Pharmacy Chain Defendants knew that their concerted and coordinated effort to subvert Tennessee state law resulted in the diversion of opioids into the illegal drug market, including the illegal drug markets in Tennessee and Baby Doe Plaintiffs' community.

L. The United States, and Tennessee in Particular, is Plagued by Rampant Opioid Abuse Driven by Defendants Perpetuating an Illegal Market for Prescription Opioids

1. Opioids are Abused and Diverted at Alarming Rates

426. The increasing demand, and high availability, of prescription opioids correlates with increased addiction, abuse, and diversion (a term used to describe redistribution of prescription drugs for illegal uses) throughout the country, including Tennessee and Baby Doe Plaintiffs' community. According to the Centers for Medicare & Medicaid Services, "'[d]rug

diversion' is best defined as the diversion of licit drugs for illicit purposes. It involves the diversion of drugs from legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary."[178]

427. Opioid misuse is a national epidemic. For example, the federal government estimated that ***11.5 million people*** had abused opioid pain relievers in 2016, including approximately ***4.4% of all people in the United States aged 12 or older.***[179] These statistics are disturbing, indicating that about 1 in 20 people in the U.S. are abusing opioids.

428. Unfortunately, the situation in Tennessee is no better, and indeed may be worse. During 2013 – 2014, the State of Tennessee estimated that nearly 5% (221,000) of adults in Tennessee used pain relievers for non-medical purposes. Of these, the State estimated that 69,100 Tennesseans were addicted to prescription opioids and required treatment for prescription opioid abuse. The other 151,900 were using prescription opioids in ways that could be harmful and may benefit from early intervention strategies.[180] Not surprisingly, opioids abuse continues to go hand in hand with an illegal drug market from which the Defendants are knowingly deriving substantial profits.

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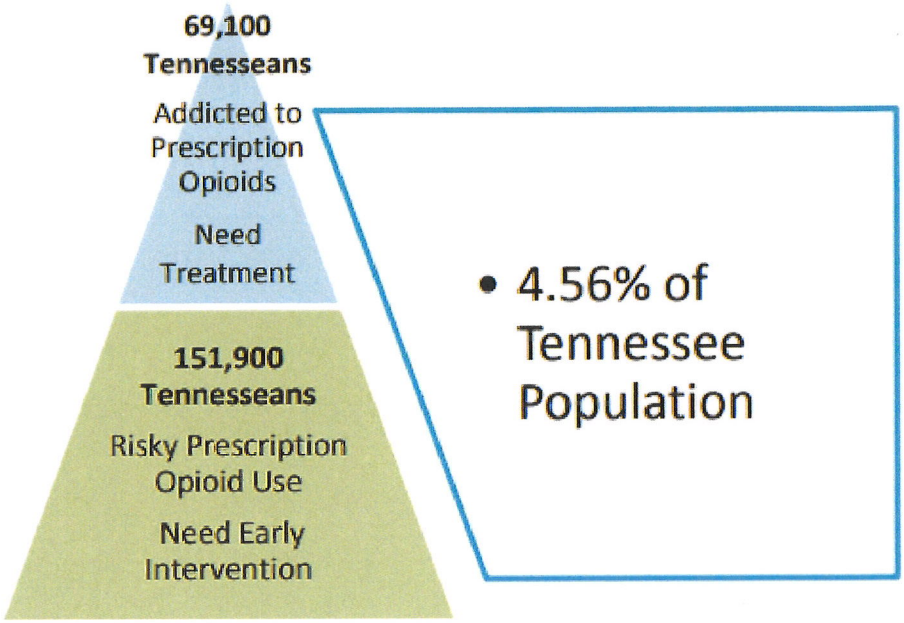
[178] "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid," Centers for Medicare & Medicaid Services (Baltimore, MD: January 2012), p. 1., accessible at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud Prevention/MedicaidIntegrityProgram/downloads/drugdiversion.pdf.

[179] https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm#opioid.

[180] "Prescription for Success: Statewide Strategies to Prevent and Treat the Prescription Drug Abuse Epidemic in Tennessee," Tennessee Department of Mental Health and Substance Abuse Services et al., (Summer, 2014), pg. 9, accessible at https://web.archive.org/web/20160414040557/https://www.tn.gov/assets/entities/behavioral-health/sa/attachments/Prescription_For_Success_Full_Report.pdf ("Prescription for Success").



2. The Defendants are Aware of a Nationwide Problem

429. Trends in opioid production, prescriptions, and usage over the last decade put drug producers and distributors on notice of a heightened risk of abuse and diversion nationwide. For example:

a. according to the Working Group Report, "[s]ince 1999, there has been no overall change in the amount of pain experienced by Americans, yet the number of prescriptions for opioids has quadrupled[;]"[181]

b. in the past two decades, the rate of opioid prescribing in the United States has increased 600%. The United States accounts for 4.6% of the world population but its citizens, by 2011, were consuming 80% of the world's opioid production;[182]

c. between 2009 and 2013, both the number of prescriptions filled per patient and the number of days of medication per prescription increased by approximately 8.4%;[183]

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[181] *Working Group Report* at 3.
[182] *Id.* (citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Misuse*, 14 Pain Physician J. 119, 120 (2011)).
[183] "A Nation in Pain" by Express Scripts, 2015.

d. nearly half (46.9%) of new opioid users who take these medications for more than 30 days in the first year continue using them for three years or longer. Signaling a particularly alarming trend, nearly 50% of these patients are only taking short-acting opioids — which can make them more prone to addiction — rather than long-acting formulations, which are designed for extended pain relief; [184]

e. on average, the patients who chronically used these medications filled 56 short-acting opioid prescriptions over three years — nearly 19 prescriptions each year;[185] and

f. prescription opioid overdose deaths quadrupled in parallel with prescription opioid sales in the United States between 1999 and 2010.[186]

430. Defendants know that production volumes of opioids skyrocketed in the last twenty-five years. In 1993, the DEA allowed pharmaceutical companies to produce 3,520 kilograms of oxycodone. In 2015, the DEA authorized production of 137,500 kilograms of oxycodone. That's a 39-fold increase in 22 years.

431. Defendants are also well-aware that for 2018, the DEA proposed a 20% reduction in the number of prescribed schedule II opioid painkillers that can be produced in the United States, with Acting Administrator Chuck Rosenberg warning that "Physicians, pharmacists, and patients must recognize the inherent risks of these powerful medications, especially for long-term use."

3. The Stream of Opioids into Tennessee is Alarmingly High and Put Defendants on Notice of Abuse and Diversion

432. Tennessee currently has the third highest statewide opioid prescription rate in the nation.[187] Indeed, Tennessee doctors in 2015 wrote more than 7.8 million opioid prescriptions — or ***1.18 prescriptions for every man, woman and child in the State***, placing Tennessee number 2 in the nation among all States for the number of opioid prescriptions per capita according to IMS

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[184] *Id.*
[185] *Id.*
[186] *Id.*
[187] *See* https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html.

Health data. By contrast, California with its population of 38.8 million people only had 0.48 prescriptions per capita in 2015. As reported by the CDC, Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. As reported by Commissioner of Health Dreyzehner in 2015 his presentation "Neonatal Abstinence Syndrome, a Tennessee Perspective," ***51 hydrocodone pills and 21 oxycodone pills were prescribed for every Tennessean*** during the period covered by that report. The same report details the dramatic, multi-fold increase in opioid prescriptions since 1999, in the absence of any meaningful increase in patients experiencing chronic pain.

433. According to the Tennessee Department of Health's Drug Overdose Dashboard, there were 7,636,112 opioid prescriptions written in Tennessee in 2016 alone.[188] The State is currently dispensing opioids at rate of 68.5 opioid prescriptions per 100 persons.[189]

434. According to IMS Health Data, the number of prescriptions of popular branded and generic opioid products containing hydromorphone, oxymorphone, oxycodone, and hydrocodone in the State of Tennessee totaled 6,148,823 for the 12-month period of September 2015 through August 2016, and 5,639,429 for the 12-month period of September 2016 through August 2017. This means in just over a two-year period, Tennesseans received more than 11.7 million of these prescriptions.

4. The Opioid Epidemic Has Devastated Tennessee Communities

435. It is difficult to overstate the human, economic, and societal toll that the opioid epidemic and associated abuse and diversion have wrought in Tennessee. The levels of opioid abuse in Tennessee are staggering: Tennessee and the Baby Doe Plaintiffs' community are awash

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[188] Tennessee Drug Overdose Dashboard.

[189] Center for Disease Control, *U.S. State Opioid Dispensing Rates, 2020*, https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html.

in opioids, plagued by high levels of opioid-induced deaths and babies born with NAS, and racked by an illegal opioids market. The flood of opioids has had – and continues to have – predictably devastating effects on Tennessee communities, including Plaintiffs' community. This includes staggering rates of addiction, opioid-related deaths, and babies born with NAS, along with the presence of criminal drug trafficking rings.

436. "Opioid overdoses, mainly from prescription drugs, are … the leading cause of the recent unexpected rise in the mortality rate of middle-aged white Americans, particularly women in rural areas, after decades of steady decline."[190]

437. As recently as 2016, the preeminent medical journal in the United States concluded that "[t][wo major facts can no longer be questioned. First, opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions….Second, the major source of diverted opioids is physician prescriptions."[191] Overdose deaths increased in Tennessee from 342 in 1999 to 2,388 in 2020, the last year for which overdoses have been calculated.[192] That represents a nearly 600% increase. Tragically, the rates of opioid deaths in Tennessee outpace the national average by a wide margin. The vast majority of overdose deaths in Tennessee – nearly 72% in 2015 – involved opioids.[193] From 2012 to 2020 (the last year for which data has been reported), Tennessee set a new record

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[190] Lenny Bernstein, et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: 'No One Was Doing Their Job'*, washingtonpost.com, Oct. 22, 2016, available at: https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

[191] "Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies," Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D., N Engl J Med 2016; 374:1253-1263 (March 31, 2016), accessible at http://www.nejm.org/doi/full/10.1056/NEJMra1507771.

[192] Tennessee Drug Overdose Dashboard.

[193] *Id.*